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GROUP 3500

**PATENT** 

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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: KALTHOFF, Robert Michael, et al.

Application No.:

10/813,918

Group No:

3626

Filed: Mar 31, 2004

Examiner:

TOMASZEWSKI, M.

For: Secure Network Gateway for Accessible Patient Data and Transplant Donor Network

**Commissioner for Patents** 

07/12/2005 SHASSEN1 00000009 502413 10813910

P.O. Box 1450

01 FC:1806

180.00 DA

Alexandria, VA 22313-1450

### THIRD-PARTY SUBMISSION IN PUBLISHED APPLICATION (37 C.F.R. § 1.99)

1. The above-identified application has been published on May 12, 2005.

This submission is being made within two (2) months from the date of publication of the above application.

**2.** Attached hereto is:

A list of patents or publications submitted for consideration by the Office, including the date of publication of each patent or publication.

A copy of each listed patent or publication in written form.

Except that only the pertinent portions of only the following listed patents and publications are being provided.

An English language translation of all the necessary and pertinent parts of any non-English language patent or publication in written form relied upon.

- 3. Service of this paper and the attachments thereto have been made on the applicant and the proof of such service is attached.
- 4. Fees Due

Fee set forth in § 1.17(p) (\$180.00)

\$ 180.00

<b>5.</b> .	Payment of Fees
	Attached is a check money order in the amount of \$
	Authorization is hereby made to charge the amount of \$180.00

to Deposit Account No. 502413.

to Credit Card as shown on the attached credit card information authorization form PTO-2038.

Charge any additional fees required by this paper or credit any overpayment in the manner authorized above.

A duplicate of this paper is attached.

Reg. No.: 36,781

Tel. No.: (225) 336-5200

Signature of Practitioner

Warner J. Delaune, Jr. Adams and Reese, LLP 450 Laurel Street, Suite 1900 Baton Rouge, LA 70801

Customer No. 021184

### **CERTIFICATE OF SERVICE UNDER 37 CFR §1.248**

I hereby certify that the above correspondence and attachments have been served upon:

TAFT, STETTINIUS & HOLLISTER LLP SUITE 1800, 425 WALNUT STREET CINCINNATI OH 45202-3957

via first class mail, United States Postal Service, proper postage prepaid, on the 7th

Warner J. Delaune, Jr.

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	ite for form 1449/PTO				Complete if Known	
Cabbana	10/10/10/11/17/07/10			Application Number	10/813,918	
THI	RD PARTY	SUE	BMISSION	Filing Date	March 31, 2004	
	List of Pul	olica	tions	First Named Inventor	Kalthoff, R. Michael	
				Art Unit	3626	
	(Use as many she	ets as n	ecessary)	Examiner Name	Tomaszewski, M.	
Sheet	1	of	1	Attorney Docket Number	6074-2	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1	Louisiana Organ Procurement Agency, "R3 (R cubed) - Referrals, Reports, and Resources - OPO Management Suite", Association of Organ Procurement Organizations, Executive Directors Meeting, October 14, 2002, Lake Buena Vista, Florida.	
	2	Louisiana Organ Procurement Agency, "The R3 Project - Referrals, Reports, and Resources", Association of Organ Procurement Organizations, Quality Improvement Meeting, October 17, 2002, San Antonio, Texas.	
	3	Louisiana Organ Procurement Agency, "Referrals, Reports, and Resources - A Database Application for OPO's", South-Eastern Organ Procurement Foundation Information Technology Seminar, March 20, 2003, Atlanta, Georgia.	
	4	Louisiana Organ Procurement Agency, "Referrals, Reports, and Resources - A Database Application for OPO's", International Transplant Nurses Society Conference, March 28, 2003, New Orleans, Louisiana.	
	5	Johnston McLamb, Inc., "R3 - Referrals, Reports, and Resources" brochure, May 2003.	
<del>,,,,</del>			

Examiner	,	Date	
Signature		Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions deducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. Do Not SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

- Oracle database platform.
- Entirely web-browser based.
- Java Script allowing for a wide variety of Written in PLSQL, HTML, Crystal and software contractors to work on system.
- No downloads or installations to operate.
- Runs just like a website.

Referrals, Reports and Resources OPO Management Suite

- Call Center.
- Referral, Recipient and Donor medical record management.
- JNOS Interface and Placement management
- Donor Registry and DMV Interface
- Management modules include system security, staff, hospital, accounting and development
- Fully Quality Assured including audit trails.
- Customizable Crystal Reporting system

- System was initially conceived by LOPA Coordinator and QA Director.
- LOPA has expended considerable resources over the past three years in development.
- Design provides for total management of the donation process and OPO.
- R<sup>3</sup> is not simply a DARTS replacement.
- New modules are relatively easy to add presently adding additional accounting, development, staff scheduling and more.

- Provides a system for non-OPO personnel to take referral calls and initiate the donation process including gathering Medical and Social data.
- Designed to function in a streamlined fashion predominantly using keystrokes and tabs.
- Automates function of determining tissue and eye ruleouts. Provides for rapid information flow to coordinators on organ eligible referrals.
- Call Center feeds data into the main R<sup>3</sup> database for use with the donation and referral process
- Also functions as message system and log.

- Provides for complete control and management of referral, donor and recipient records.
- Maintains contact and contract information for all hospitals, transplant centers, eyebanks, etc.
- Provides complete QA trail for record.
- Records may be updated from any location with Internet access.
- Coordinators and technicians can begin and complete paperwork in the field.
- Electronic records can be reviewed by Transplant Centers.

- Provides a system for 'top down' management of security and access.
- ED 'panic button' locks down system.
- Levels of access are fully controlled and designed by managers.
- All security settings and look up table values are controlled and managed by the OPO ED designate.
- security holes or patches (which Microsoft® is Oracle® is famous for rock solid security - no famous for!)

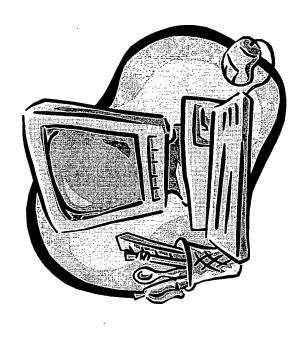
- System provides invoicing information directly to accounting - increasing cash flow
- Letters to donor families, hospital staff, etc. are automatically generated.
- Automatic system backup both off site and internally within call center.
- online at specified and password protected url. Transplant centers can review donor records
- Double redundant backup operating systems.

- Hosted solution provides full access to Crystal Enterprise® reporting system
- reports and provides a system for simple System can provide any number of set development of customizable reports.
- Crystal recognized as the leading report software company in the world.

- System provides a full record of each entry to a file including time, date and user.
- Designed to comply with the requirements of both HIPAA and FDA.
- various tissue agencies and eyebanks Ruleout criteria set as determined by
- Provides for locking of records once QA accepted.

- Scalable system allows for easy addition of modules and growth of users and data
- Can be customized by the OPO to meet specific needs.
- Development cost can be shared across multiple OPOs.
- Useable as a hosted (shared with separate data base) or stand alone solution

- the cost of the software design, Oracle® and Available as a hosted solution which shares customization of look and feel and look up Crystal® licensing. This still allows for tables while providing a completely separate database for each OPO
- customizable application to run on Also available as a stand alone independent server systems



## The R3 Project

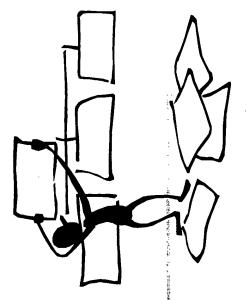
# Referrals, Reports and Resources

Presented by:

AOPO QI Meeting, October 2002 Kathy Pizzolato, RN, CPTC

STETTERS REPORTS and Resources	ind Resources	System Messages for 10/14/2002  Message posted on 10/01/2002 12:01 am Welcome to R3!!  Message posted on 10/01/2002 12:00 am Have an idea for improving or changing hor	Mair Massage posted on 10/01/2002 12:01 am Wessage posted on 10/01/2002 12:01 am Wessage posted on 10/01/2002 12:00 am Message posted on 10/01/2002 12:00 am Have an idea for improving or changing how R3 works? <u>Click here</u> to send a message to us!
And the second s	Welcome to the LOPA Referrals. Reports and Resources		
ent User KPIZZOLA		R.R.R. Version 0.99 Copyright © 2002 LOPA	Dete/Time: 10/14/02 17:55:5





- Call Center.
- Referral, Donor and Recipient medical record management.
- UNOS Interface and Placement.
- Donor Registry and DMV Interface.
- Management modules include system security, staff, hospital, accounting and development.
- Fully Quality Assured including audit trails.
- Customizable Crystal Reporting system.



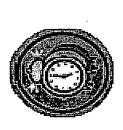
# Time Involved & Issues

- Year One Design (October 1999)
- System was initially conceived by two LOPA Coordinators (now ED and QA Manager).
- Very time consuming
- Dealing with Software Company with no prior knowledge of business
- Liberties taken by software company without LOPA authorization
- Year Two Implementation (January 2001)
- System delivered incomplete and yet functioning
- Continued time consuming pace with poor outcome
- Web Client based system (download required)





- Year Three Starting over (January 2002)
- New software company
- 9 month delivery date
- Extremely time consuming due to new project
- LOPA has expended considerable resources over the past three years in development.
- Delivered project October 1, 2002
- A few conv ersion issues after delivery
- 2 hurr icanes allowed delays



# Time Involvement to come

- Year Four New Modules (January 2003)
- New modules will be relatively easy to add
- Accounting
- Development
- Staff scheduling
- Transplant Center
- And more.



# Results - System Software





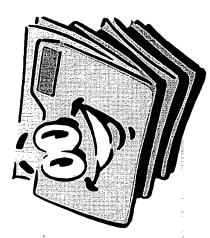
- Entirely web-browser based.
- Written in PLSQL, HTML, Crystal and Java software contractors to work on system. Script allowing for a wide variety of
- No downloads or installations to operate.
- Runs just like a website.

### Results – Call Center Module



- including approaching families and gathering Medica Provides a system for non-OPO personnel to take referral calls and initiate the donation process and Social data.
- Automates function of determining tissue and eye ruleouts. Provides for rapid information flow to coordinators on organ eligible referrals.
- Call Center feeds data into the main R<sup>3</sup> database for use with the donation and referral process.
- Also functions as message system and log.

## Records Management Results –



- Provides for complete control and management of referral, donor and recipient records.
- Maintains contact and contract information for all hospitals, transplant centers, eyebanks, etc.
- Provides complete QA trail for record.
- Records may be updated from any location with Internet access.
- Coordinators and technicians can begin and complete paperwork in the field.
- Electronic records can be reviewed by Transplant Centers.

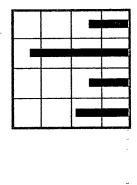
## Security and Management **Results** –

- Provides a system for 'top down' management of security and access
- ED 'panic button' locks down system.
- Levels of access are fully controlled and designed by managers.
- controlled and managed by the OPO ED designate. All security settings and look up table values are
- security holes or patches (which Microsoft® is Oracle® is famous for rock solid security - no famous for!)

### Results – Additional Features



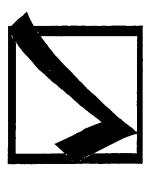
- Letters to donor families, hospital staff, etc. are automatically generated.
- Transplant centers can review donor records online at specified and password protected
- System provides invoicing information directly to accounting - increasing cash flow
- Automatic system backup both off site and internally within call center.



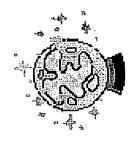
# Results - Reporting

- Full access to Crystal Enterprise® reporting system.
- development of customizable reports (RAS or reports and provides a system for simple System can provide any number of set Smart reporting).
- Trained Crystal report writer (me!) always available.

### Results – Quality Assurance

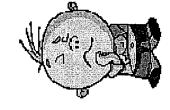


- System provides a full record of each entry to a file including time, date and user.
- Designed to comply with the requirements of both HIPAA and FDA.
- Ruleout criteria set as determined by various tissue agencies and eyebanks.
- Provides for locking of records once QA accepted.



# Future Expectations

- Smooth operating system that will house all needed data for agency
- Improved statistical analysis
- Crystal Enterprise (RAS Smart Reporting)
- SPSS
- QA tool "no blanks" allowed
- information from Transplant Centers. Improved recipient follow up







### South-Eastern Organ Procurement Foundation

presents its

Bi-Annual Meeting



March 19-22, 2003

HIGHLIGHTS

- InCytes About Hepatic & Pancreatic Cell Transplantation
- OPO Information Technology Seminar
- Medical, Surgical & Financial Complications
   Surrounding Organ Transplantation
- ASHI/SEOPF Southeastern Regional Workshop

The Scientific Session on Complications is jointly sponsored by Wake Forest University School of Medicine and SEOPF



### Thursday, March 20, 2003

### Information Technology Seminar: How OPOs Are Meeting the Need

(Salon IV) 8:30 am - 4:30 pm

Moderator: Dan Stockdreher, MPH, CPTC

8:30 - 9:00 am Continental Breakfast

9:00 - 9:10 am Opening Remarks

Dem Lalisan, MBA, CPTC, Alabama Organ Center

9:10 - 9:40 am Internet In Your Hands: The Future of Communications

Rudy Siegel, LDT Systems

9:40 - 11:30 am Processing Referral Calls: Call Center Technologies

Deidre Ellis, General Manager, Statline Kim Zasa, Gift of Life, Michigan

Kathy Pizzolato, RN, CPTC, Louisiana Organ Recovery Agency

14:30 - 4:00 pm Open Luncheon Committee Meetings

•OPO / Tissue & Cell Technology (Jackson)

•Scientific Affairs / Liver / Pancreas (Nashville)

1:00 - 2:15 pm Database Applications for Public & Professional

Education, Family Services, Quality Assurance/Compliance

Applications, Billing and Reporting

Tracker: Craig Myrick, RN, CPTC, Intermountain Organ Rec. Sys.

DARTS: Jason Soley, Gift of Life, Philadelphia R Cubed. Kathy Pizzolato, RN, CPTC, LOPA

2:15 - 2:45 pm Use of PDAs in the Field: Replacing the Coordinator's Bible

Joseph Sharp, CPTC, LifeGist

2:45 - 3:00 pm Break

3:00 - 4:30 pm Organ Sharing Using the Internet: Organ Transplant

Response System: Start Up Experience and Beta Test Results

Tom Mone, One Legacy

Lori Paskiewicz, Gist of Life, Michigan

David Lewis, RN, BSN, Ohio Valley Life Center

4:30 pm Adjournment

Referrals,

CL

Reports and Resources:

# A Database Application for OPOs

Presented by:

Kathy Pizzolato, RN, CPTC

SEOPF Information Technology Seminar

March 20, 2003

### Overview

- Call Center.
- Referral, Recipient and Donor medical record management.
- UNOS Interface and Placement management.
- Donor Registry and DMV Interface.
- human resources, hospital database, and lookup Management modules include system security, tables.
- Quality Assurance including audit trails.
- Customizable Crystal Reporting system.

## System Software

- Oracle database platform.
- Entirely web-browser based.
- Java Script allowing for a wide variety of software contractors to work on system. Written in PLSQL, HTML, Crystal and
- No downloads or installations to operate.
- Runs just like a website.

### Design

- System was conceived by a coordinator and Director of Recovery.
- LOPA has expended considerable resources over the past three years in development.
- Design provides for total management of the donation process and the OPO.
- hospital development and quality assurance. presently designing staff scheduling, UNET, New modules are relatively easy to add -

#### Call Center

- Provides a system for non-OPO personnel to take referral calls and initiate the donation process.
- flow to coordinators on organ eligible referrals. Automates function of determining tissue and eye rule outs. Provides for rapid information
- database for use with the donation and referral Call Center feeds data into the main R<sup>3</sup> process.
- Designed to function in a streamlined fashion predominantly using keystrokes and tabs.
- Also functions as message system and log.

### Data Management

- Provides for complete control and management of referral, donor and recipient records.
- Coordinators and technicians can begin and complete paperwork in the field.
- Data may be updated from any location with Internet access.
- Electronic records can be reviewed by Transplant Centers.
- Maintains contact and contract information for all hospitals, transplant centers, eye banks, etc.
- Provides complete QA trail for each record.

## Security and Management

- Provides a system for 'top down' management of security and access.
- Levels of access are fully controlled and designed by system administrator.
- All security settings and look up table values are controlled and managed by the system administrator.
- ED 'panic button' locks down system.
- Oracle® is famous for rock solid security no security holes or patches.

### Other Features

- Letters to donor families, hospital staff, etc. are automatically generated.
- Ability to add attachments to records.
- Correspondence Log for Family Services communication.

#### Reporting

- Use either Crystal Enterprise® reporting system or basic Crystal Reports.
- Basic reports come with the package.
- reports and provides a system for simple System can provide any number of set development of customizable reports.
- Crystal is recognized as the leading report software company in the world.

### Quality Assurance

- System provides a full record of each entry to a file including time, date and user.
- Designed to comply with the requirements of both HIPAA and FDA (part 11).
- Rule out criteria is managed by system administrator to accommodate specific tissue agencies and eye banks.
- Provides for locking of records once QA accepted.

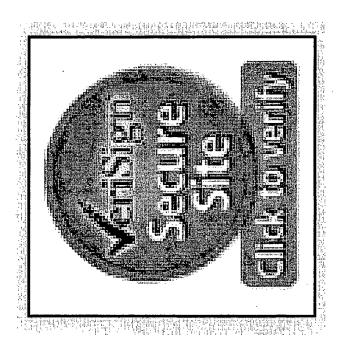
#### Advantages

- of modules and growth of users and data. Scalable system allows for easy addition
- Can be customized by the OPO to meet specific needs.

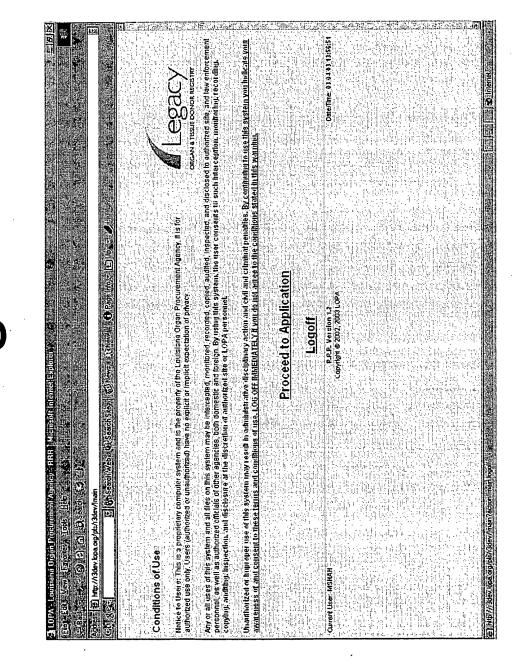
#### Options

- Available as a stand alone customizable application to run on independent server systems.
- customization of look and feel and look up of software design, Oracle® and Crystal® Potentially a hosted solution (shared cost tables while providing a completely separate database for each OPO licensing). This still allows for

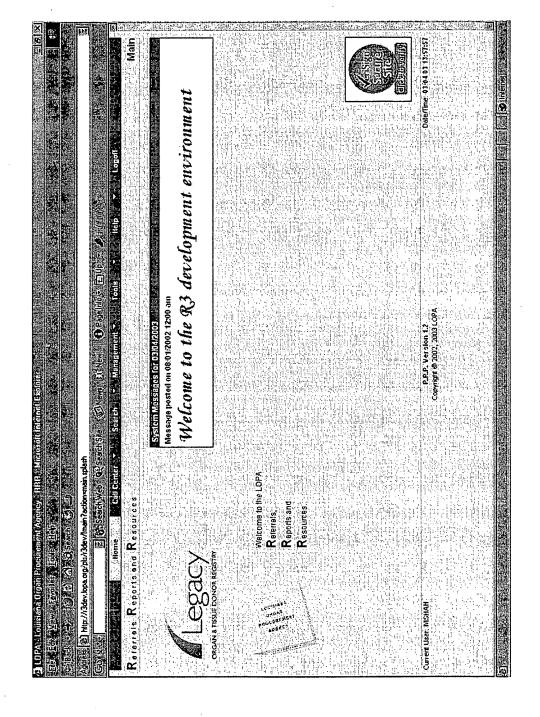
## Secure Communications



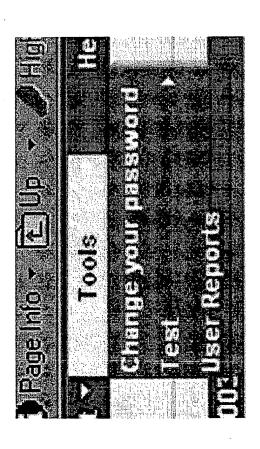
## Initial Logon Screen



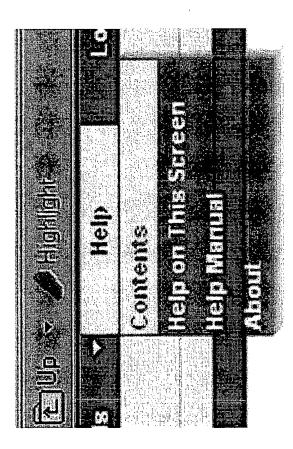
#### Main Menu



#### Tools Menu



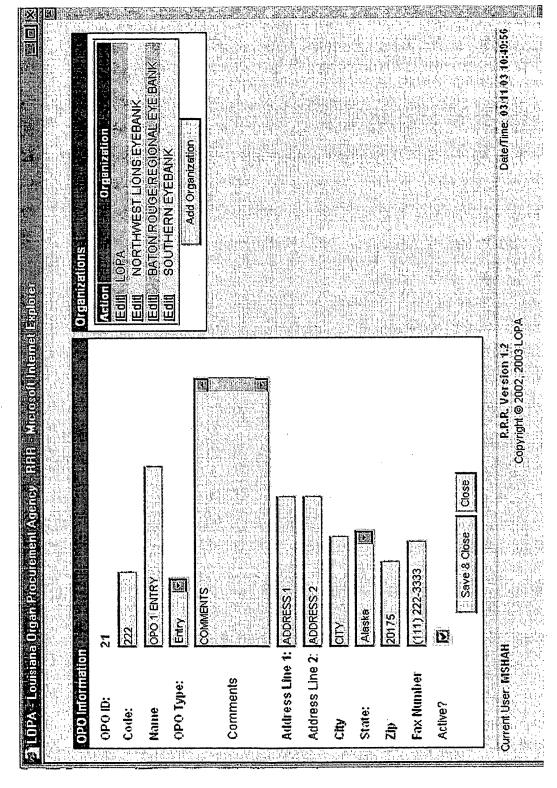
#### Help Menu



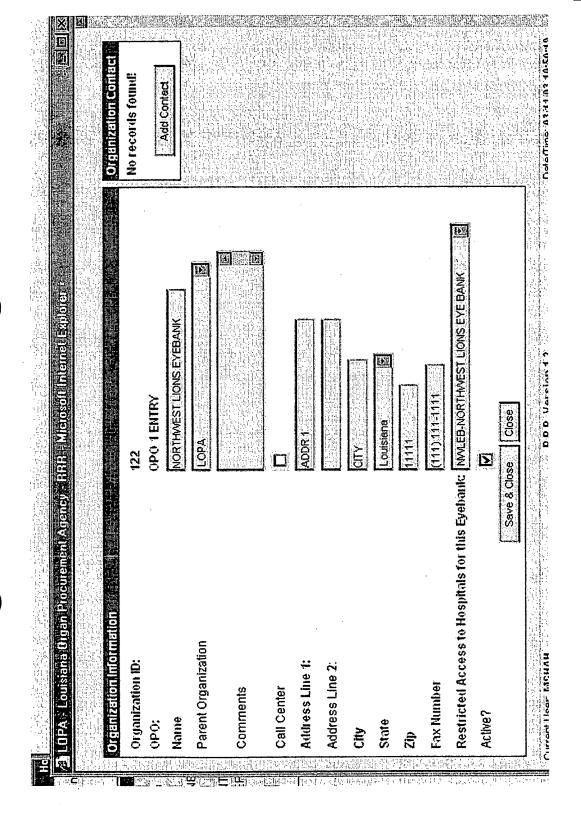
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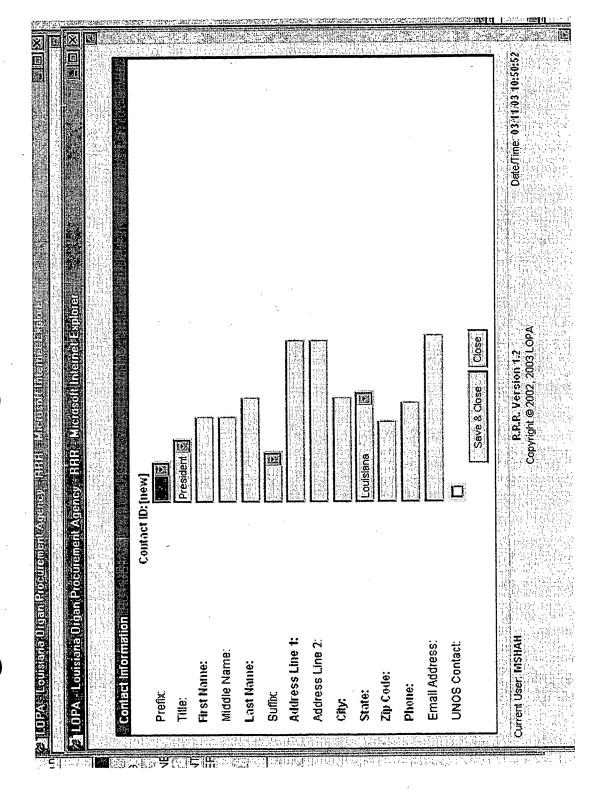
### Management: OPO



# Management: Organization



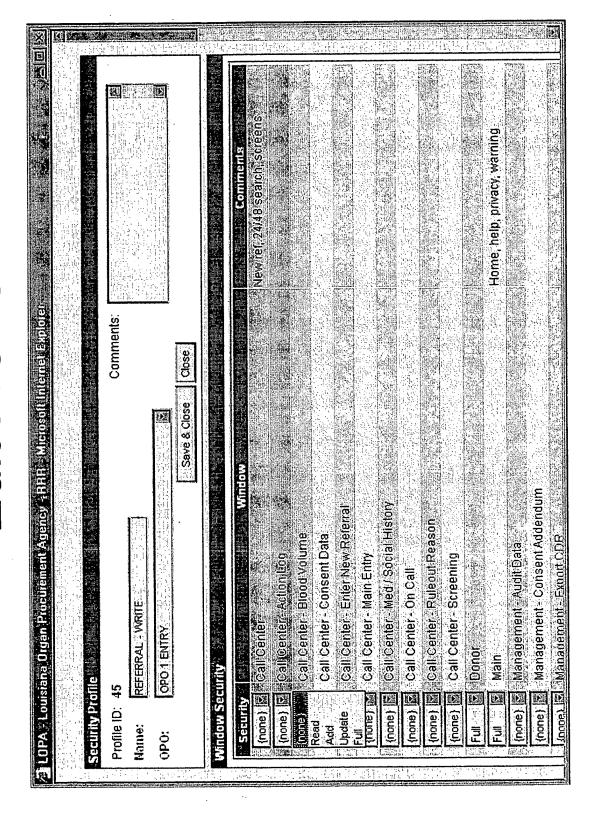
# Management: Organization Contact



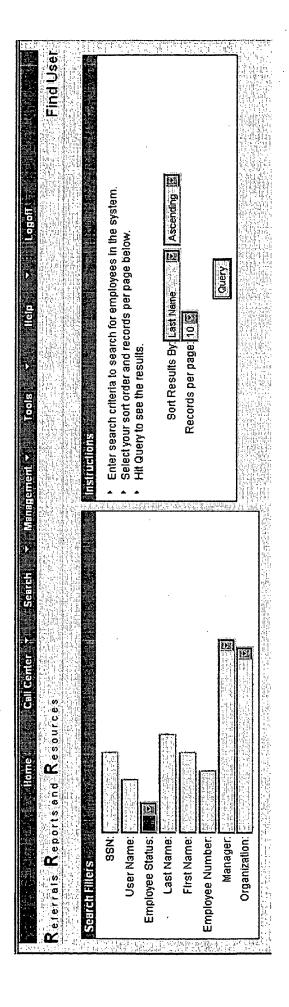
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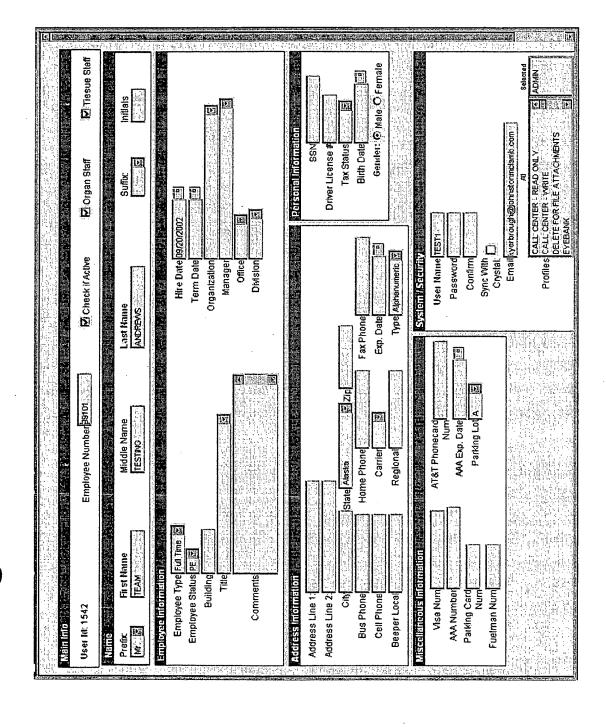
### Management: Security Profiles Edit Profile



### Management: Users



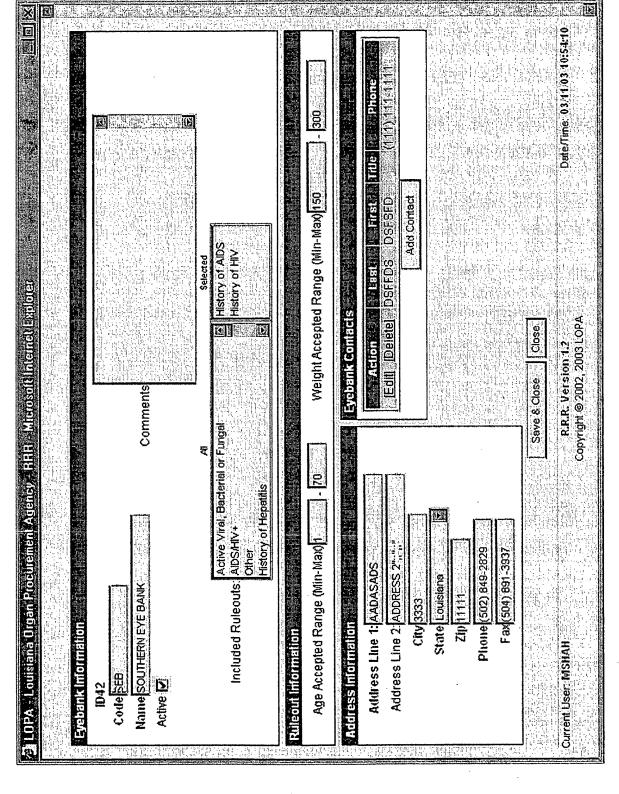
# Management: Users - Add/Edit



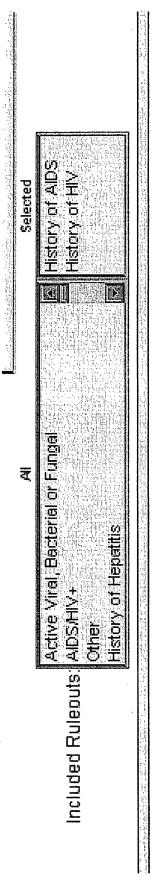
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## Management: Edit Eyebank



### Management: Eyebank – Eyebank Ruleouts



## Management: Messaging

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# Management: Import Registry

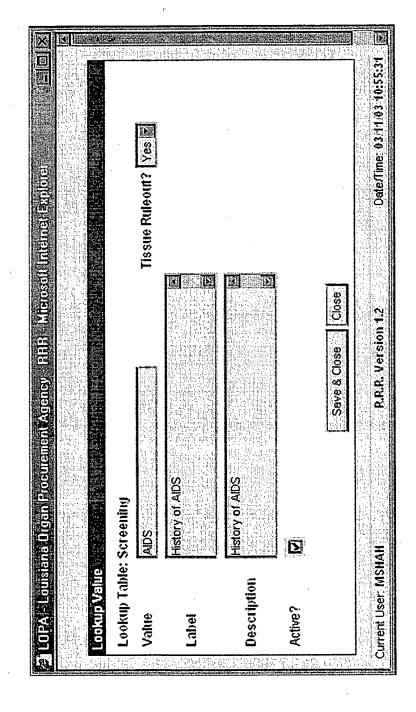
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## Management: Lookups

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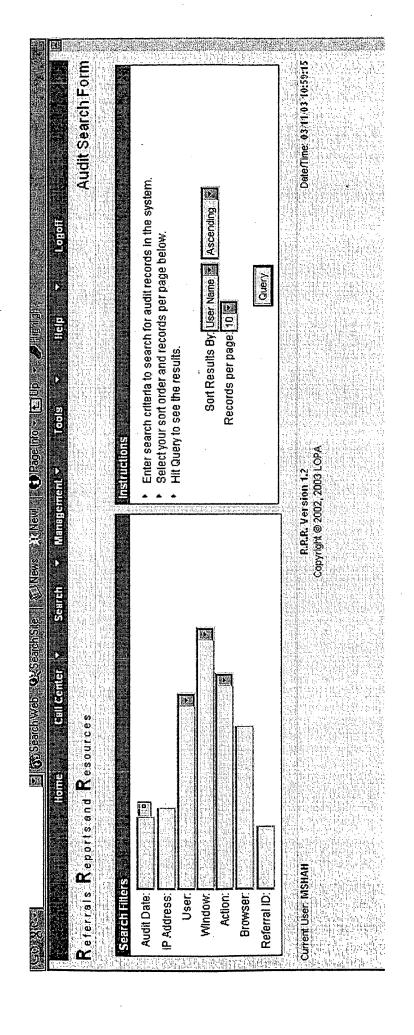
### Management: Lookup Example Screening



### Management: Help

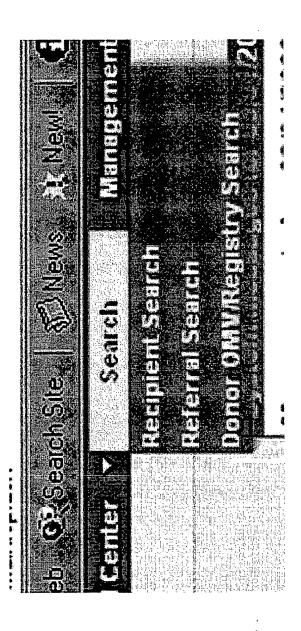
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## Management: Audit Data

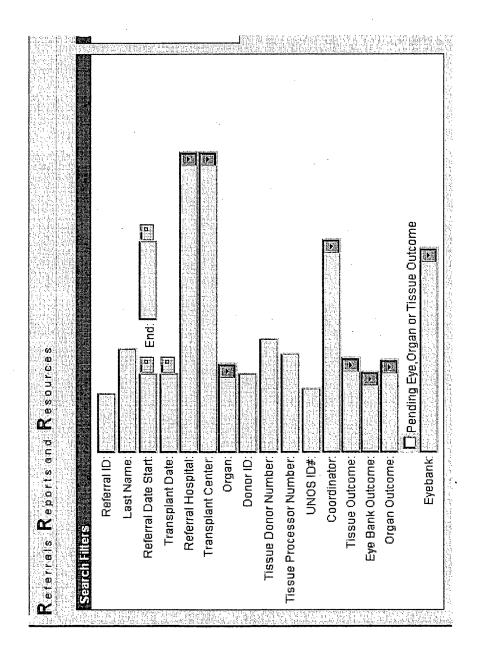


### Entering and Editing Clinical Information

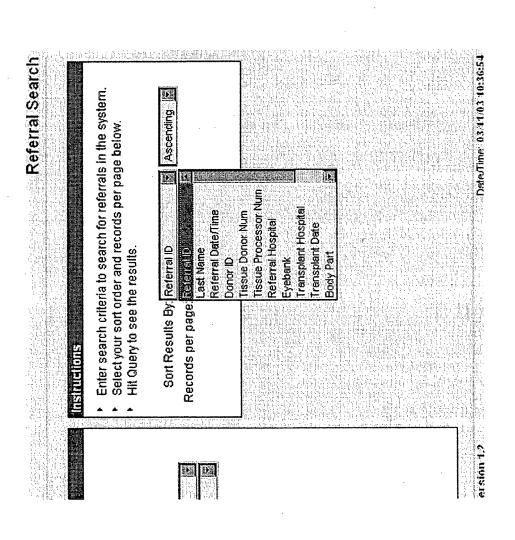
#### Search Menu



# Referral Search Parameters



### Sort Criteria Referral Search



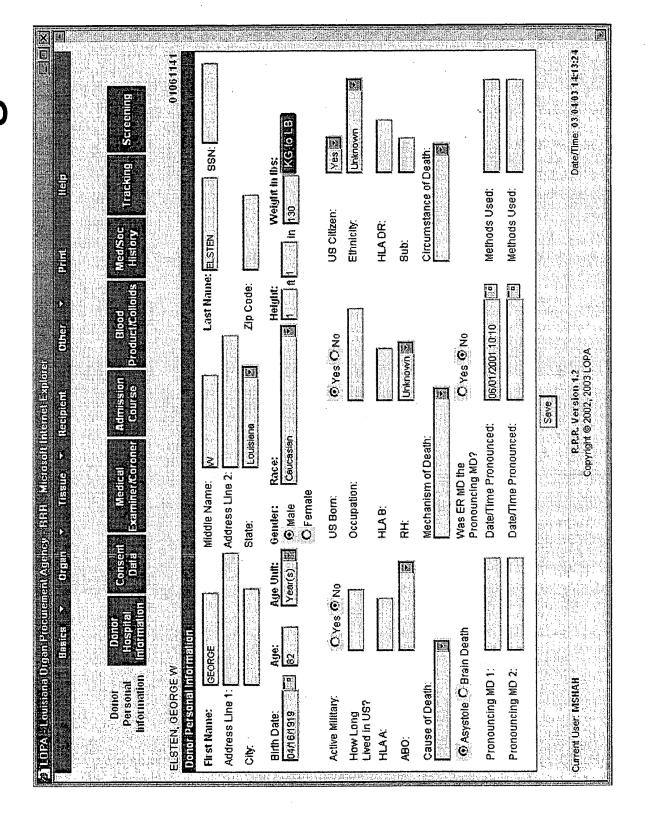
#### Referral List

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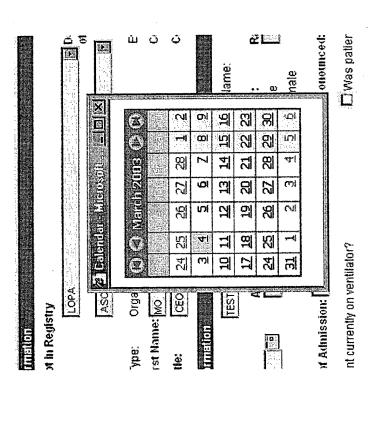
### Referral Basics Menu

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# Referral Basics: Main Page



## Entering a date

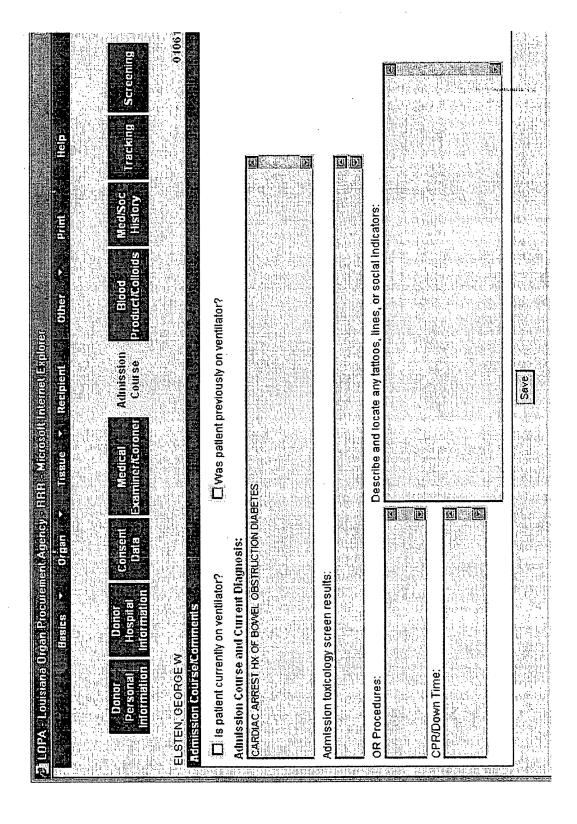


#### LOPA

## Referral Basics: Hospital Information

City. MORGAN CITY Hospital State: L. Phone:  Unit: ER Provider#: 1  Bate/Time of Referral: Departure B: Date/Time: Date/Time: Contact's First Name: Contact's Phone:	Donor Donor Do	Holing Conseption Data	nt   Medical   A	Admission Blood Medisoc Troducticolloids History Troducticolloids History	MediSoc Trac	racking Screening Screening Oriostitat
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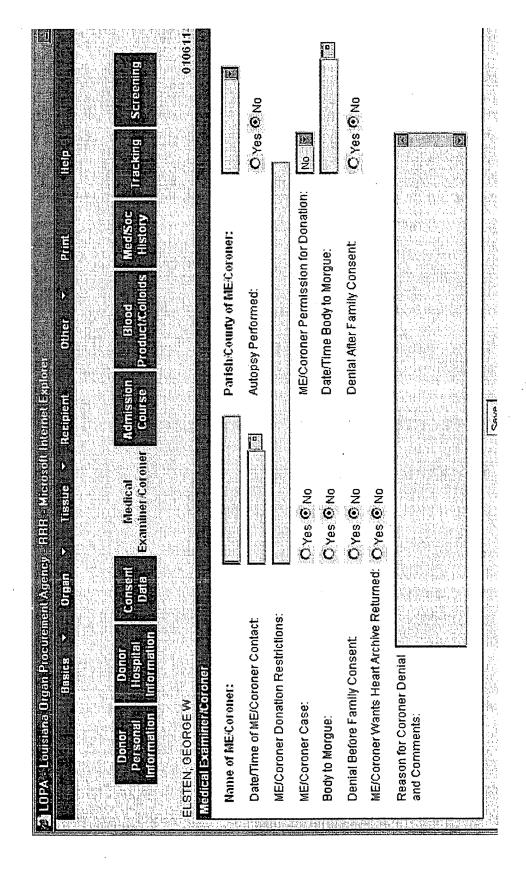
# Referral Basics: Admission Course



# Referral Basics: Consent

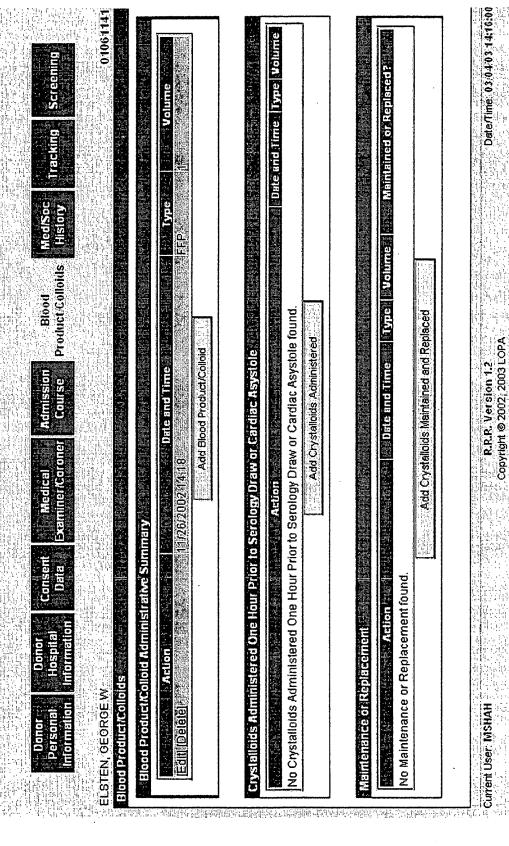
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# Referral Basics: ME/Coroner

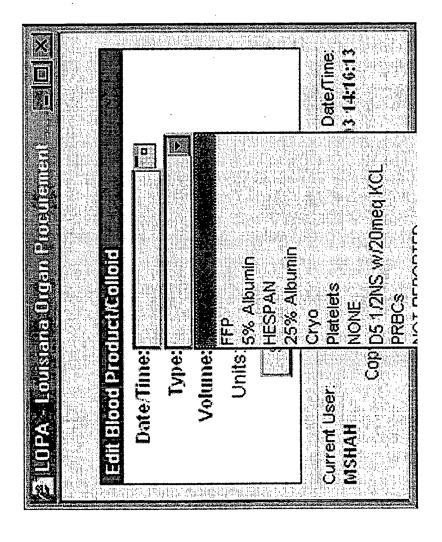


#### LOPA

#### Referral Basics: Blood Products/Colloids



### Referral Basics: Entering a **Blood Product**



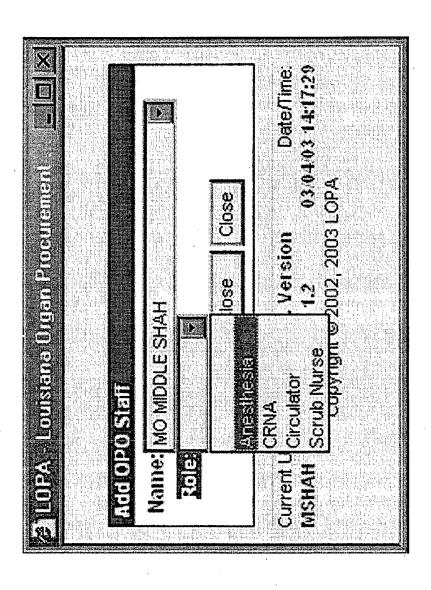
## Referral Basics: Medical/Social Questionnaire

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# Referral Basics: Tracking

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# Referral Basics: Adding staff



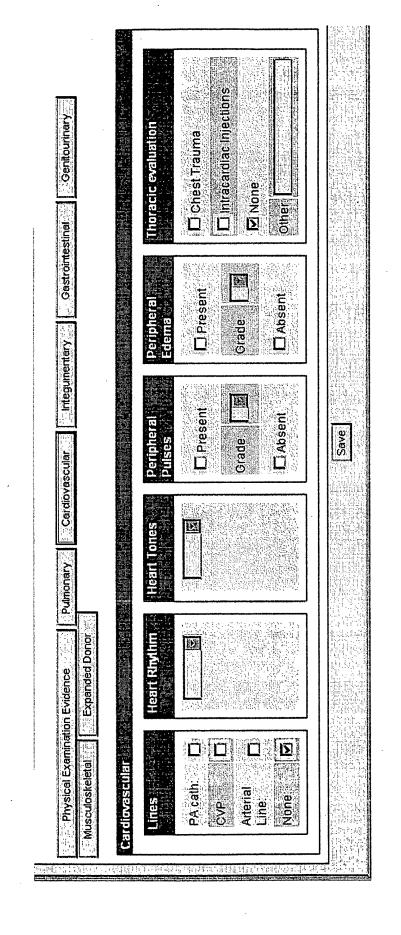
### Organ Menu

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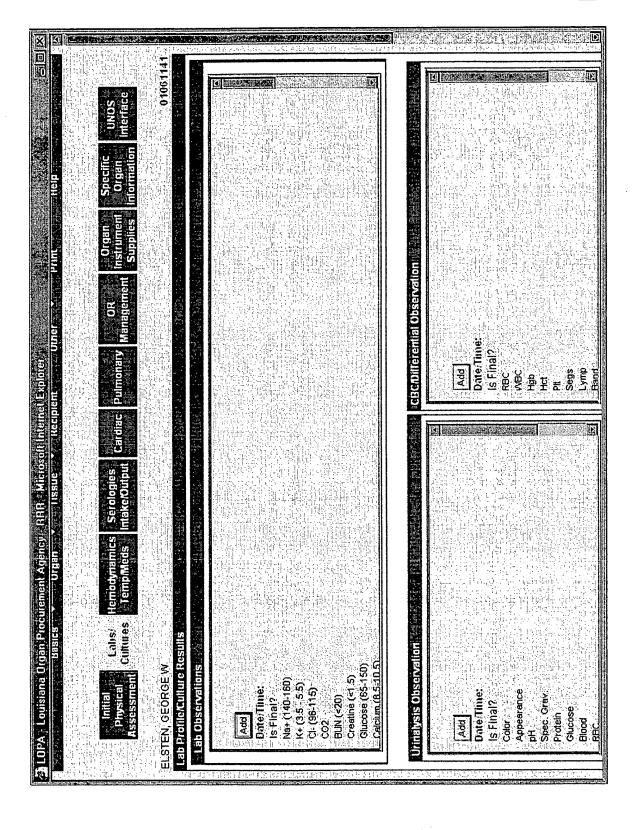
#### Organ: Initial Physical Assessment

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Initial Physical Assessment  Body  Identified by:		Person Identifying:	
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Physical Examination Evidence			
Physical Exam Name	Answer		Self ** Comments   12   Self **   Se
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Anal tears/perianal warts	Unknown 📧		
White spots in mouth.	Unknown 📧		

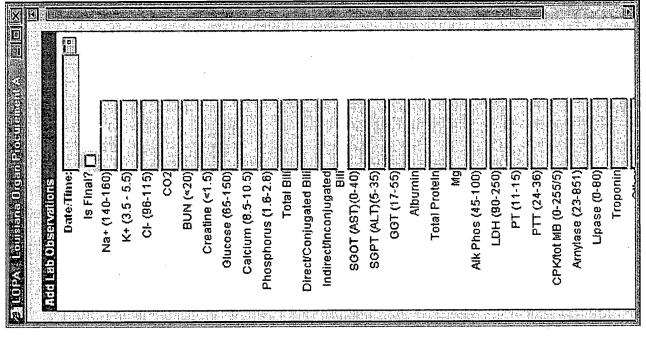
### Assessment -Cardiovascular Organ: Initial Physical



## Organ: Labs/Cultures



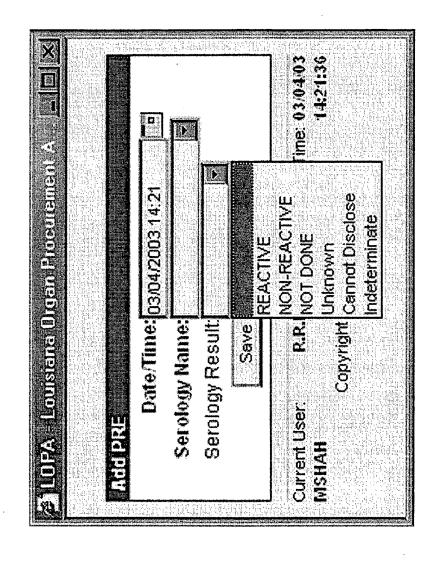
## Organ: Adding a lab



## Organ: Serology Results

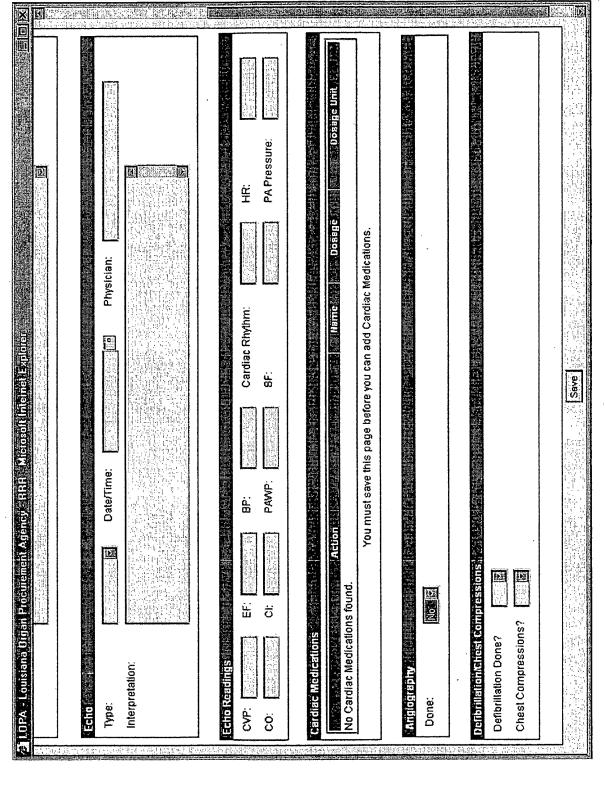
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### Organ: Serology – Adding a serology

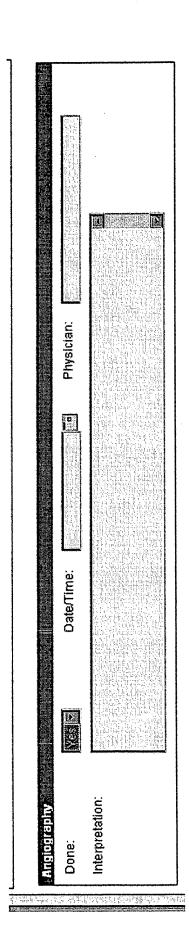


LOPA

## Organ: Cardiac Data



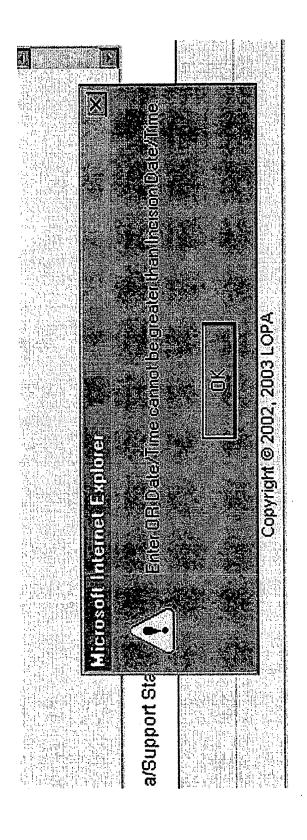
#### Organ: Cardiac (dependant fields)



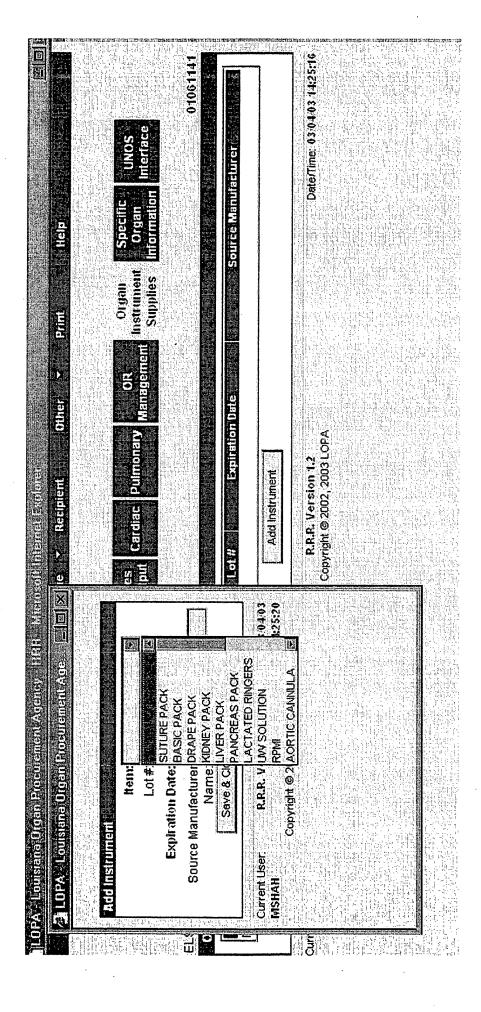
## Organ: OR Management

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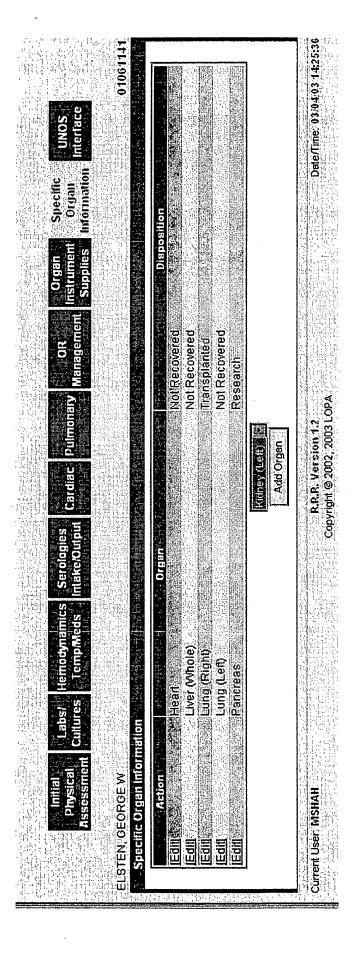
### Organ: OR Management Example Validation



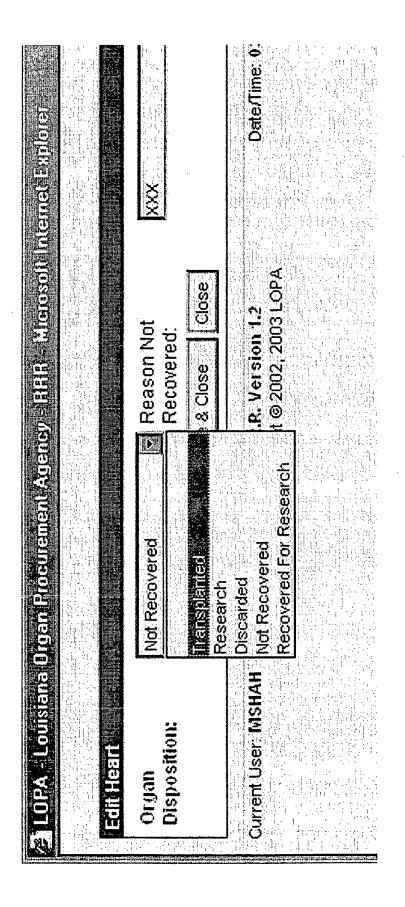
# Organ: Instrument Supplies



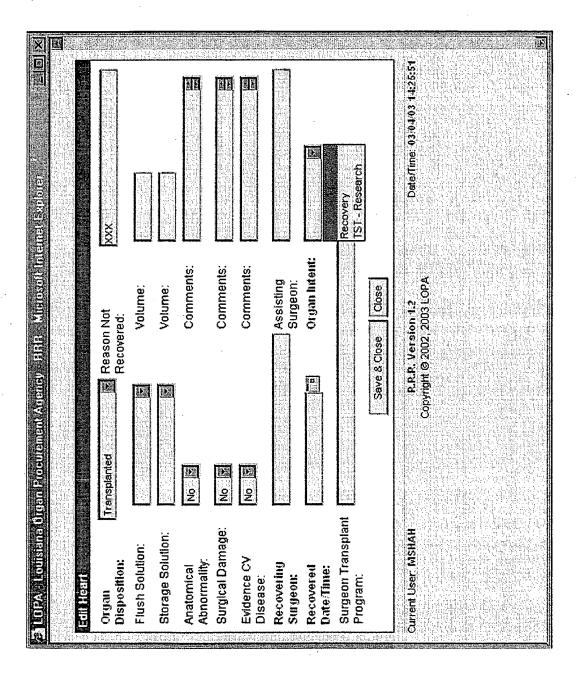
#### Organ: Specific Organ Information



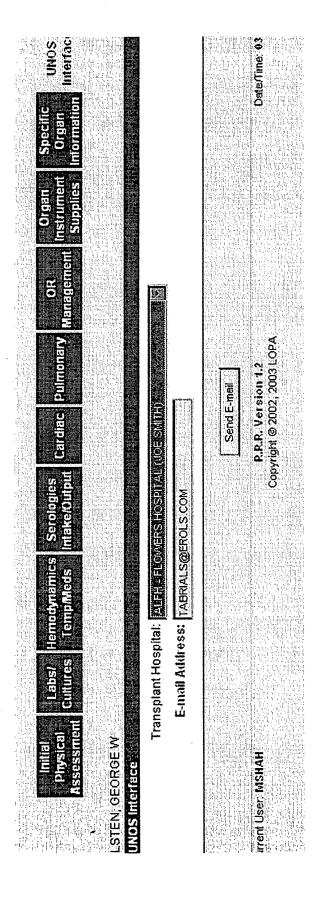
# Organ: Specific Organ- Heart



# Organ: Specific Organ - Heart



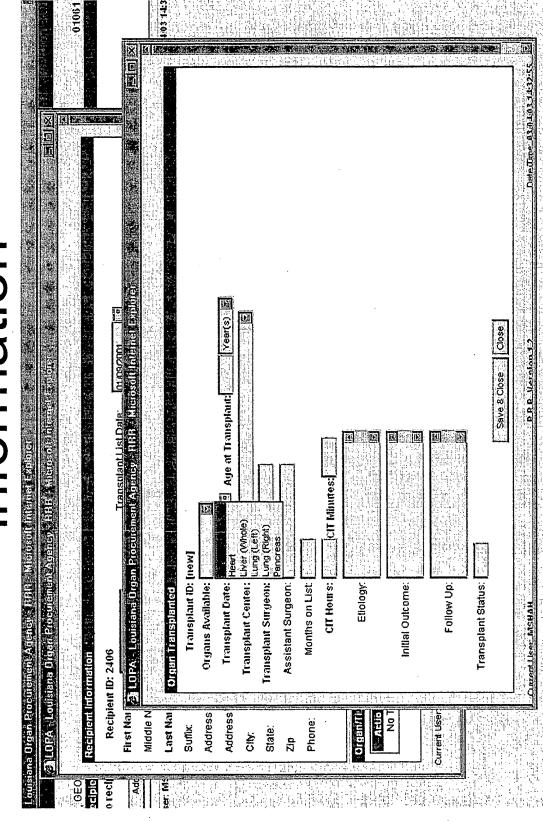
## Organ: Placement



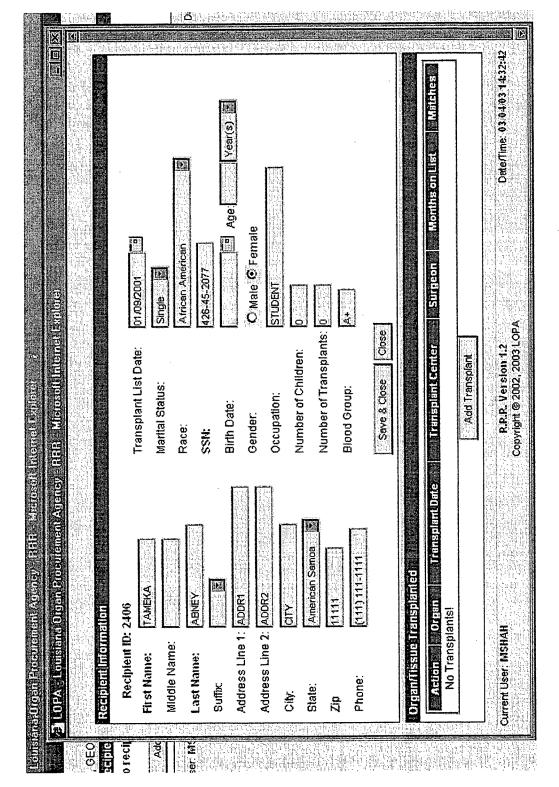
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## Recipient: Entering transplant information



# Recipient: Edit Recipient



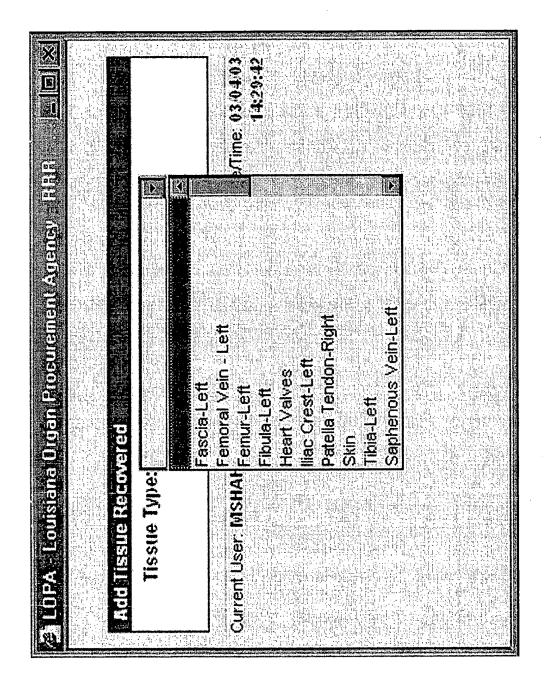
### Tissue Menu

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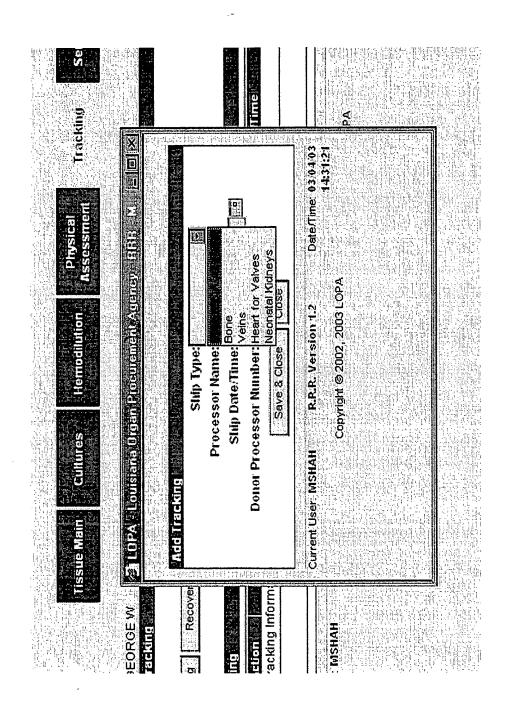
# Tissue: Add Tissue Recovered



# Tissue: Physical Assessment

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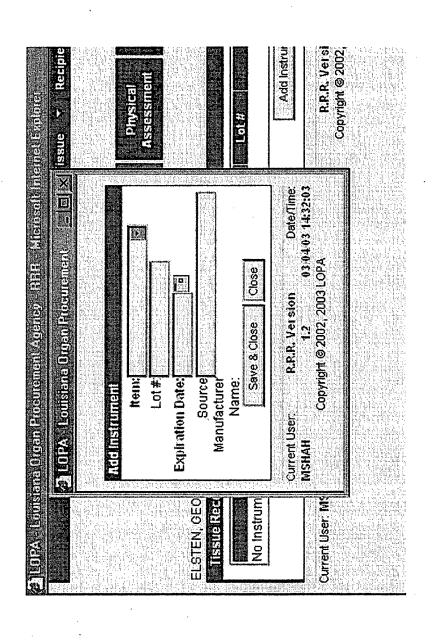
## Tissue: Tracking



## Tissue: Tissue Team

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# Tissue: Tissue Recovery Supplies



### Referral Tools

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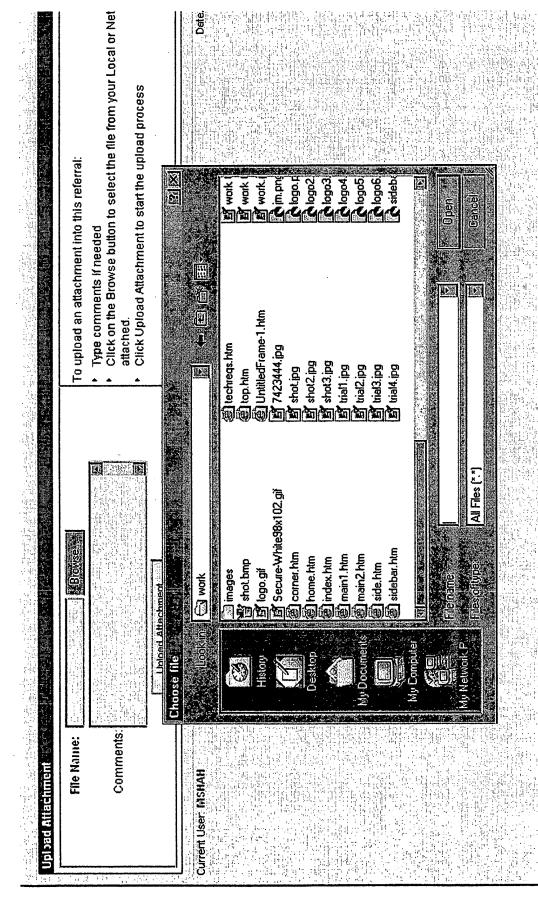
# Referral Tools: Correspondence

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errai Correspondence

Date/Time: 03/04/03 14:33:18 R.R.R. Version 1.2 copyright @ 2002, 2003 LOPA Save & Close Current User: MSHAH

# Referral Tools: Add Attachment



# Quality Assurance: Locking Records

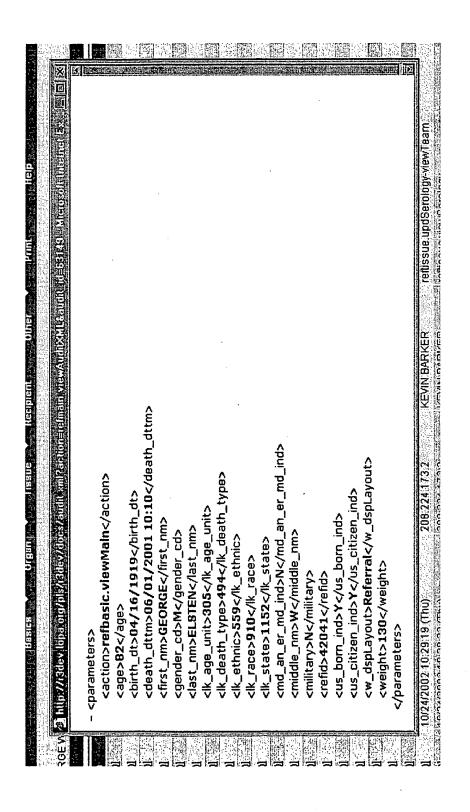
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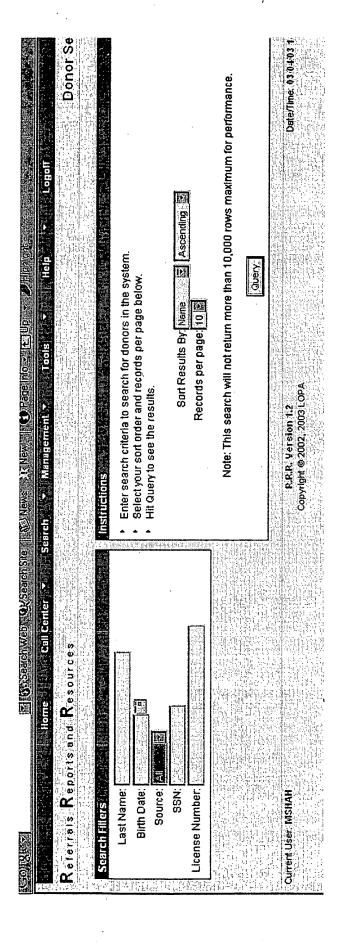
# Referral Tools: Generate Letter

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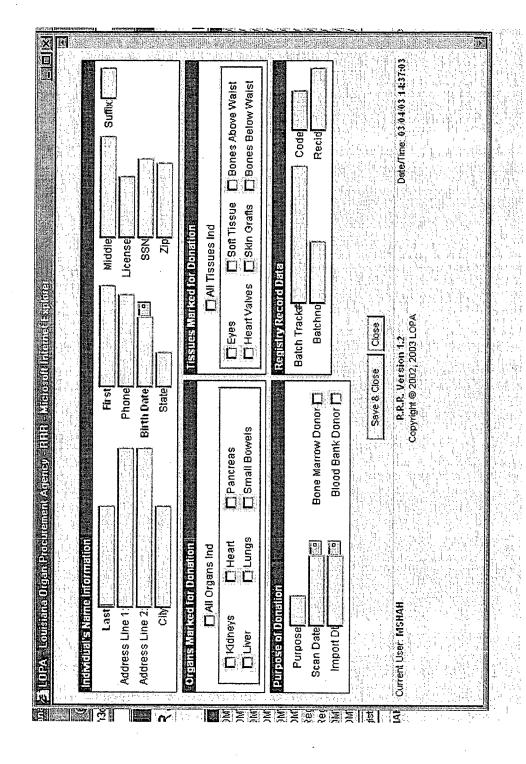
## Other: Generate Letter

and your family during your time of loss. I hope it gives you some comfort to know that so many people will be helped by Although the loss of your, GEORGE, can never be justified, I hope the knowledge that his gift will help many people, can bring you some solace. From a donation such as the one you made, it is possible that up to fifty people may benefit from consolants that smill sionificantly immrove the mality of their lives. Though nothing can ever take GFORGE's place, there On behalf of the staff at the Louisiana Organ Procurement Agency, I would like to express my deepest sympathy to you Close Reset 🚰 LOPA - Louisiana Organ Procurement Agency - RRR - Microsoft Internet Explorer Letter Text Print Individual Print All No recovered itssue data was found for this referral Save All farch 04, 2003 your courageous decision to donate. March 04, 2003 GEORGE W Action . General Genera er MSHAH Genera Genera Genera General Genera Genera < |General . Genera Genera Gener ste Letter No Existin Current L

### Registry Search

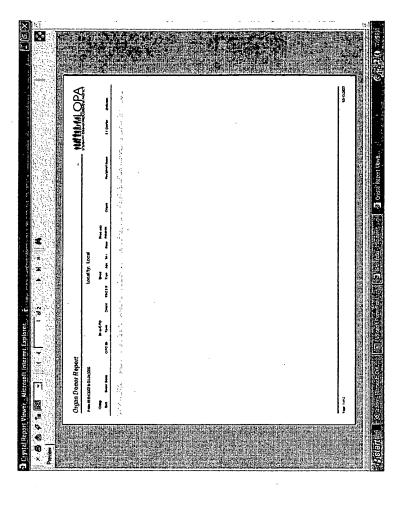


## Add Registry Records



### Basic Reports

- Monthly Referral Report
- Organ Donor Report
- Tissue Donor Report
- Call Center Report
- Death Record Review Report



### Clinical Forms

- Organ Donor Form
- Based off the AOPO Organ Donor Form
- Recipient Information Form
- Tissue Donor Form

## For More Information

- www.johnstonmclamb.com/r3
- Email: R3@johnstonmclamb.com
- Materials available:
- Demo site
- Hardware specifications

### **Questions?**



Thank You!

A

73

Referrals, Reports and

Resources:

A Database Application for OPOs

Presented by: Kelly Ranum, RN, CPTC Transplant Festival March 28, 2003

#### Overview

- Call Center.
- Referral, Recipient and Donor medical record management.
- UNOS Interface and Placement management.
- Donor Registry and DMV Interface
- Management modules include system security, tables. human resources, hospital database, and lookup
- Quality Assurance including audit trails.
- Customizable Crystal Reporting system

## System Software

- Oracle database platform.
- Entirely web-browser based.
- Written in PLSQL, HTML, Crystal and software contractors to work on system. Java Script allowing for a wide variety of
- No downloads or installations to operate.
- Runs just like a website.

#### Design

- System was conceived by a coordinator and Director of Recovery.
- LOPA has expended considerable resources over the past three years in development.
- Design provides for total management of the donation process and the OPO.
- New modules are relatively easy to add hospital development and quality assurance. presently designing staff scheduling, UNET,

#### Call Center

- Provides a system for non-OPO personnel to take referral calls and initiate the donation process
- Automates function of determining tissue and flow to coordinators on organ eligible referrals eye rule outs. Provides for rapid information
- Call Center feeds data into the main R<sup>3</sup> database for use with the donation and referral process
- Designed to function in a streamlined fashion predominantly using keystrokes and tabs.
- Also functions as message system and log.

## Data Management

- Provides for complete control and management of referral, donor and recipient records
- Coordinators and technicians can begin and complete paperwork in the field.
- Data may be updated from any location with Internet access
- Electronic records can be reviewed by I ransplant Centers.
- Maintains contact and contract information for all hospitals, transplant centers, eye banks, etc.
- Provides complete QA trail for each record.

# Security and Management

- Provides a system for 'top down' management of security and access.
- Levels of access are fully controlled and designed by system administrator.
- All security settings and look up table values are administrator. controlled and managed by the system
- ED 'panic button' locks down system.
- Oracle® is famous for rock solid security no security holes or patches

### Other Features

- Letters to donor families, hospital staff, etc. are automatically generated.
- Ability to add attachments to records.
- Correspondence Log for Family Services communication.

#### Reporting

- Use either Crystal Enterprise® reporting system or basic Crystal Reports.
- Basic reports come with the package.
- System can provide any number of set development of customizable reports. reports and provides a system for simple
- Crystal is recognized as the leading report software company in the world.

## Quality Assurance

- System provides a full record of each entry to a file including time, date and user.
- Designed to comply with the requirements of both HIPAA and FDA (part 11).
- Rule out criteria is managed by system tissue agencies and eye banks. administrator to accommodate specific
- Provides for locking of records once QA accepted.

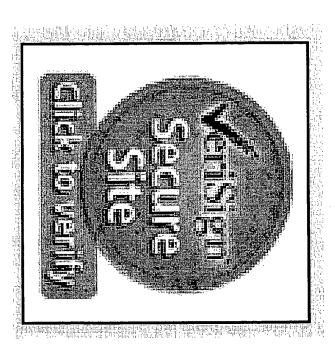
### Advantages

- Scalable system allows for easy addition of modules and growth of users and data.
- Can be customized by the OPO to meet specific needs.

#### **Options**

- Available as a stand alone customizable systems. application to run on independent server
- Potentially a hosted solution (shared cost separate database for each OPO. of software design, Oracle® and Crystal® licensing). This still allows for tables while providing a completely customization of look and feel and look up

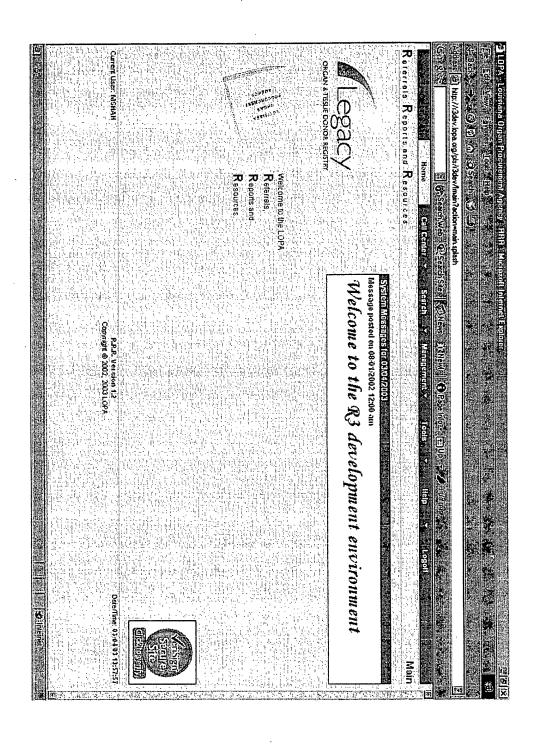
## Secure Communications



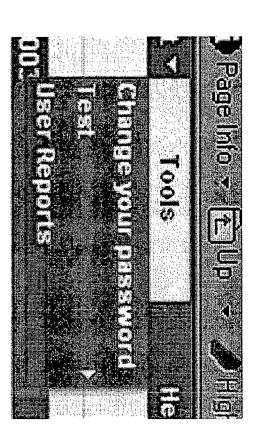
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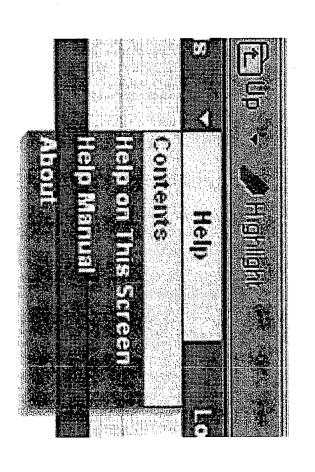
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#### Tools Menu



#### Help Menu



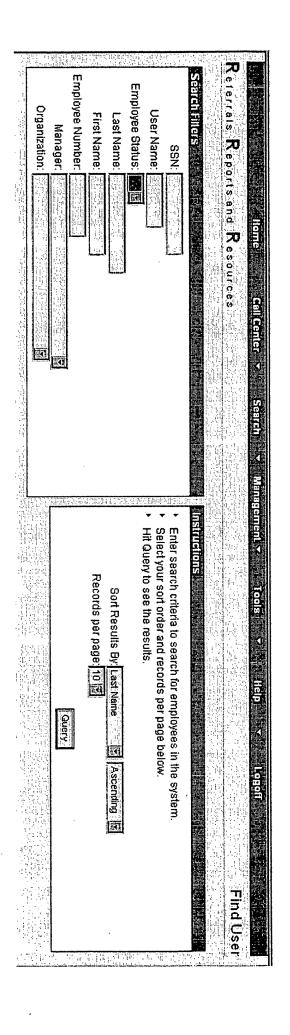
# Management: Security Profiles

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## Management: Users



### Management: Users — Add/Edit

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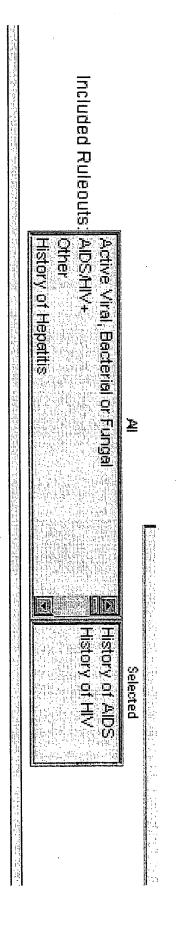
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# Management: Edit Eyebank

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### Management: Eyebank – Eyebank Ruleouts



# Management: Messaging

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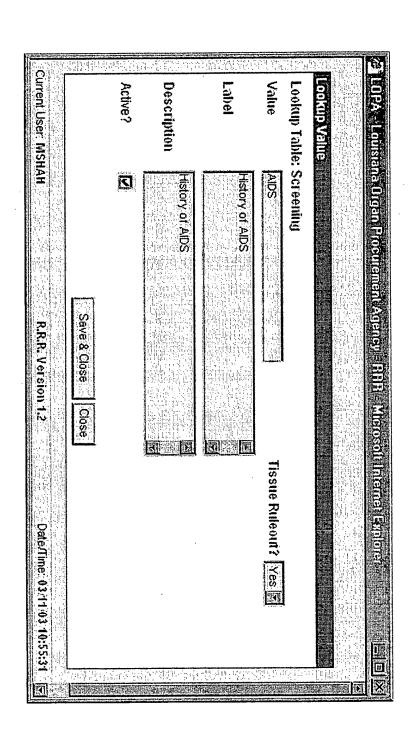
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### Management: Lookups

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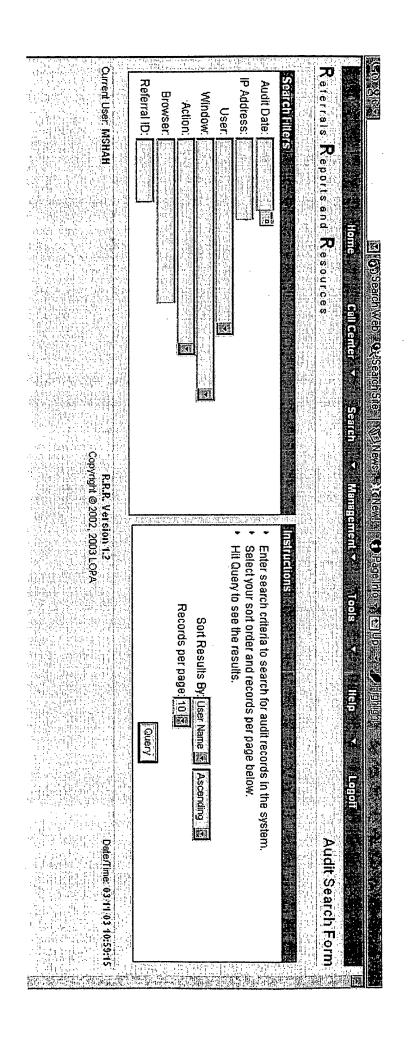
#### Management: Lookup Example: Screening



### Management: Help

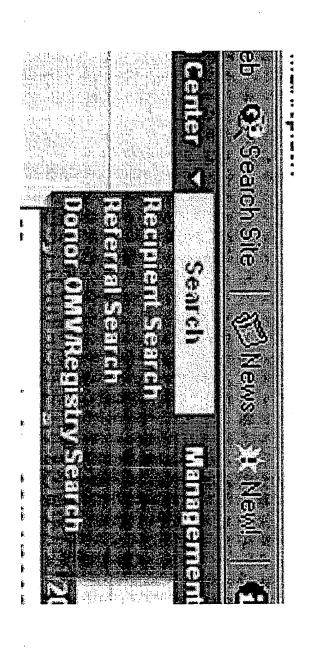
Ourent User: MSHAH	Management - Imports Management - Interview Questions Management - OPOs / Organizations Management - Security Profiles Management - System News and Messages Management - Users Management - Users Management - Web Action Maintenance Management - Web Menu Maintenance Message Log Recipient	Management - Audit Osta Management - Consent Addendum Management - Export CDR Management - Export Rules Management - Eyebanks Management - Hep Window Maintenance	Call Center Call Center - Action Log Call Center - Blood Volume Call Center - Consent Data Call Center - Enter New Referral Call Center - Main Entry Call Center - Main Entry Call Center - Med / Social History Call Center - On Call Call Center - On Call Call Center - Screening Call Center - Screening Call Center - Screening Call Center - Screening Domor	Reports and Re
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### Management: Audit Data

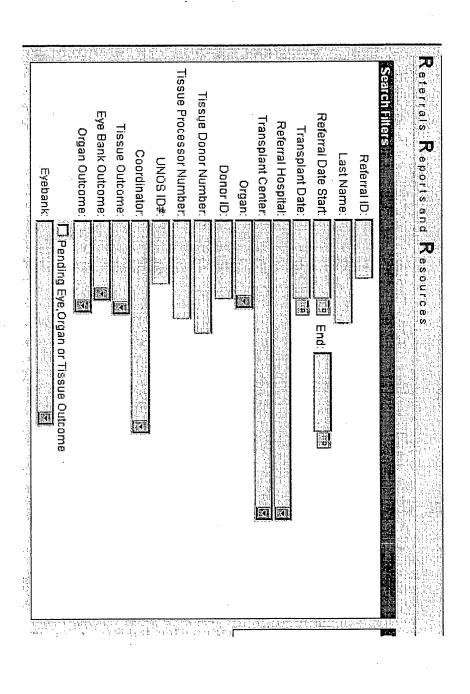


### Entering and Editing Clinical Information

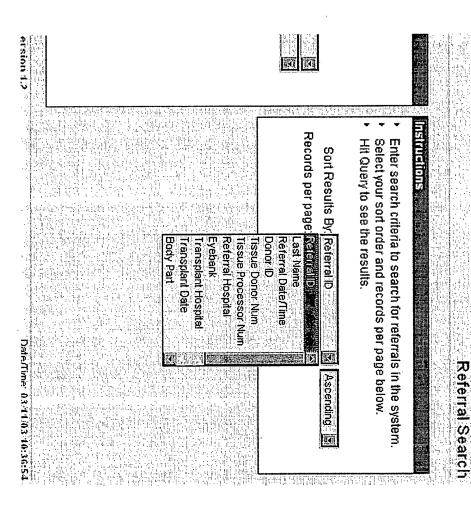
#### Search Menu



# Referral Search Parameters



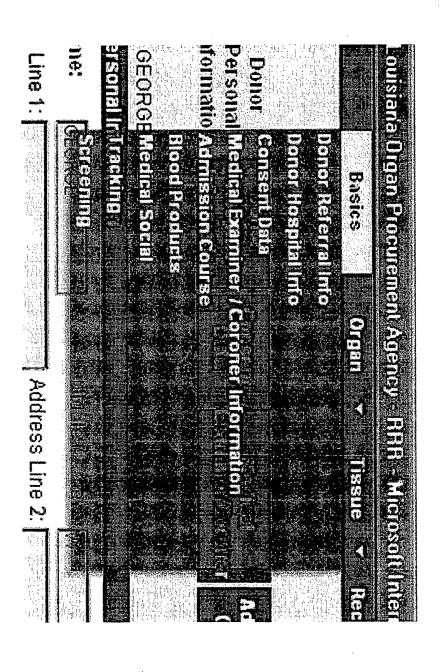
### Referral Search Sort Criteria



#### Referral List

	[17] J. Barton, M. C. Chang, and J. C. Chang, and J. C. Chang, and J. C. Chang, and J. Chang, and		Add New Referral
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	RIVERSIDE MEDICAL CENTER	<u> </u>	LEGIN 01061311TATE JAMES
		OLINE 06/01/2001 13:25	
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	Rows 1 - 10 of 4, 153		
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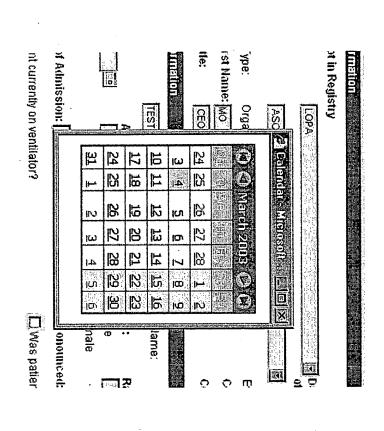
### Referral Basics Menu



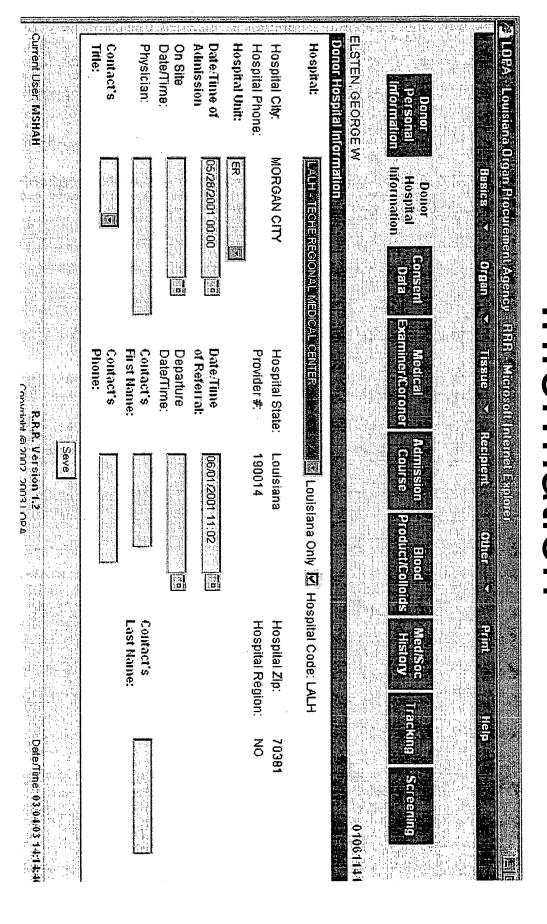
# Referral Basics: Main Page

Current User, MSHAH	Pronouncing MD 1: Pronouncing MD 2:	Cause of Death:  Asystole C Brain Death	HLA A:	Active Military: How Long Lived in US?	Birth Date: Ay D4/16/1919 B		Personal Information ELSTEN, GEORGE W	2) LDPA: - Louisiana Qigan Pigotirem Hasics:
		Death		OYes @ No	Aye: Aye Unit: 82 Year(s) 图		Hospital Data on Information ====================================	
R.R.C.\ Copyright @ 2	Date/Time Pronounced: Date/Time Pronounced:	Mechanism of Death:  Was ER MD the Pronouncing MD?	HLA B:	US Born: Occupation:	Gender: Race:  G Male Ceucesian  O Female	Middle Name: W	Examine (Coroner	neni Ageney - ARAN Microsoft Internet Esplane - Accipient - Recipient - Accipient - Admission   Admission
Save R.R.R. Version 1.2 Copyright © 2002-2003 LOPA	05.01 /2001 10:10 <u>113</u>	O Yes O No	Unknown R	© Yes O No	Height:	Last Manne: ELSTEN  Zip Code:	Prod	lore; Other Blood
	Methods Used: Methods Used:	Circumstance of C	HLA DR: Bub:	US Citizen: Ethnicity:	Weight in 130		lac	Print   Help
Date/Time: 03/04/03:14:13:24		of Death:		Yes E Unknown E	(In the:	SSN:	King Screening	

### Entering a date



#### Referral Basics: Hospital Information

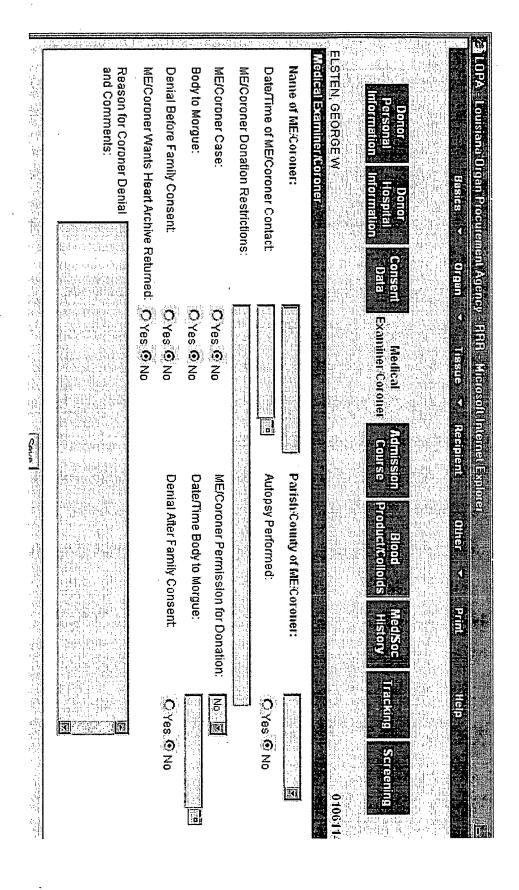


# Referral Basics: Admission Course

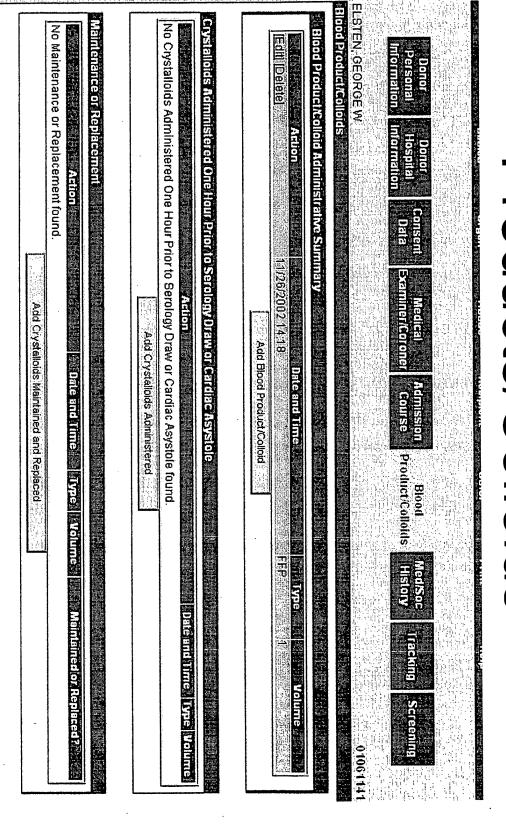
### Referral Basics: Consent

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LE Bones/Soft Tissue	Kidneys:	infestines	Hearivaives	Heart	Eyes/Cornea	Other		I grant my consent for the surgical removal of organs and tissues from <u>GEORGE W ELSTEN</u> for the purpose as indicated below:	Consent Given For 图 图 图 图 图 图 图 图 图 图 图 图 图 图 图 图 图 图 图	NOK State:	NOK Address Line 1	Next of Kin:	Donor Card: Unknown	General Approacher:	Joint Approach?	Reapproach By LOPA? Deco	Discussed By Name:	Approached By Name:		ELSTEN, GEORGE W
CYes © No	Cives @ No	OYes © No	OYes @ No	Oyes @ No	ONes ONO	OYes O No	Requested	)val of organs and tissi		440-1441				<u>ব</u>		Decoupled? No E App				
							Reason not Requested	Sues from <u>GEORGE W ELSTE</u>	Funeral Home:	NOKZIp:	NOK Address	Next of Kin Unknown Relationship:	Date/Time of Consent		Corsent Date	Appropriate Setting? No E			Approached By Data	
OYes @ No	∥Oyes ⊚ No ∏	OYes © No	Oyes © No	Oyes ONO		Oyes O No	Obtained	N for the purpose as		The state of the s										
							Resson not Obtained	indicated below:		Phone:	NOK City.									01061141

# Referral Basics: ME/Coroner



#### Referral Basics: Blood Products/Colloids

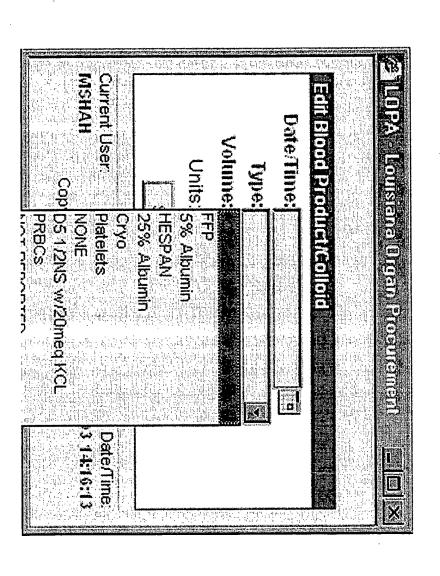


Current User: MSHAH

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Date/Time: 03/04/03/14:16:00

#### Referral Basics: Entering a **Blood Product**



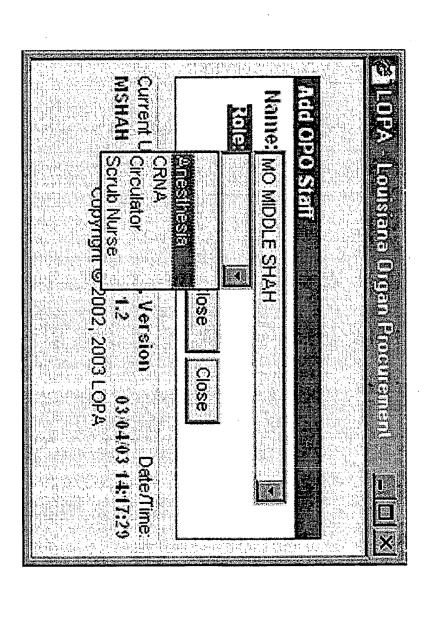
### Referral Basics: Medical/Social Questionnaire

О	also de signa de compositions	nii ee in	E Joan	(Sharah			karsinkiriya:	nagan e <b>s</b>
Ourient User: MSHAH	Comments:	Answer:	Question 1a: Version 2 question 1 <u>[Guidance]</u>	Question #1 General Health Information	Next   Last   Next   Ne	Comments	Are there other individuals that may provide additional information regarding these medical and behavioral history questions?	Do you feel you knew the deceased well President No answer questions regarding medical/behavioral history?
Saye  R.R.R. Version 1.2  Copyright © 2002, 2003 LOPA				ion		Other Individual Phone:		Oyes O No Name: Name
Deteлime: 03:04:03 14:16:37			4.7Y R. 3.144	- S. J.				

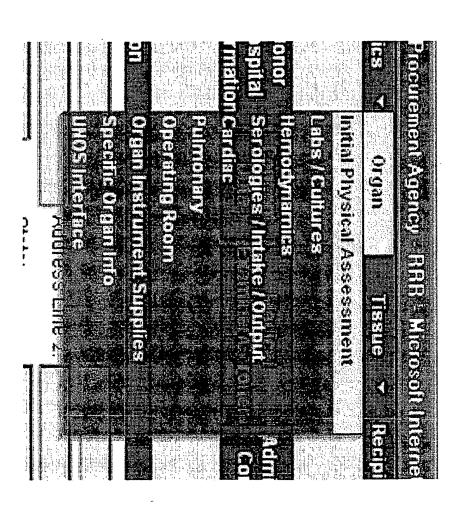
#### Referral Basics: Tracking

Add Hospitel Staff Add OPO Staff	No Personnel found.	Personnel :	Medical Record #: Cancer Free Interval:	Referral Taken By: Organ Referral Coordinator.	Tissue Donor  Number:  Coordinator:	UNOS ID#: CDR Record Key:	Import/Pay Back From: N/A Think the second s	Eyebank Name: N/A	Eye Bank Outcome Reason: Ruled Out Eye Bank Ruleout Reason:	Eye	Organ Shutdown Reason: Organ Medically Suitable	Organ Outcome Reason: Rued Out 등 Organ Ruleout Reason:	Tissue Shutdown Reason: Tissue Medically Suitable	Tissue Outcome Reason: Ruleaton Tissue Ruleout Reason:	Record is Not in Registry
			Information of the second of t	BYRON FOURNET								Age		Age in the control of	

# Referral Basics: Adding staff



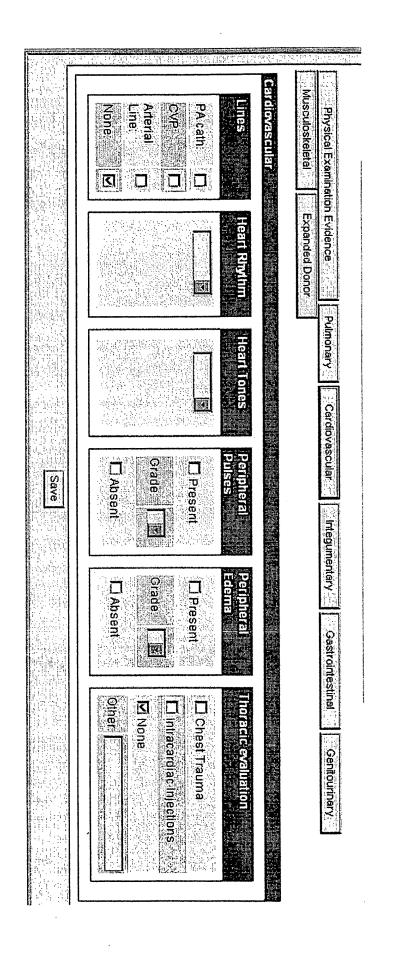
#### Organ Menu



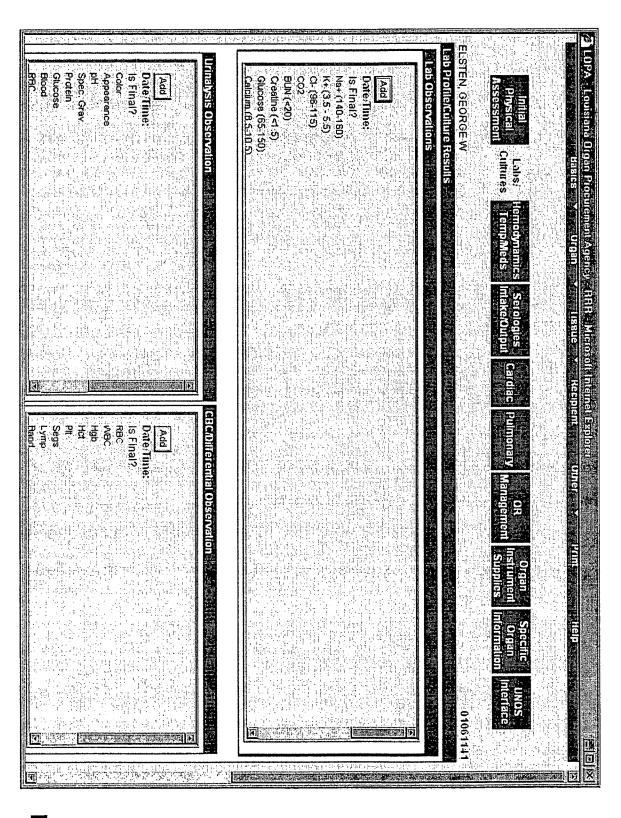
#### Organ: Initial Physical Assessment

・ 「	White spots in mouth
	Ana lears/penana wans
	Infection Unknown
	Jaundice Unknown
	ymph nodes
	Blue/purple spots Unknown
《《···································	Genital lesions
一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个一个	Trauma to tissue retrieval sites Unknown 🗷
	Non-medical injection of drugs Unknown 🔯
The second s	Physical Exam Name Answer
Cardiovascular Integumentary Gastrointestinal Centiourinary	Physical Examination Evidence Pulmonary  Musculoskeletal Expanded Donor
	Comments:
Examination Date/Time:	Performed  By:
	dentified by:
	Initial Physical Assessment
	ELSTEN, GEORGE W
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#### Assessment -Cardiovascular Organ: Initial Physical



### Organ: Labs/Cultures

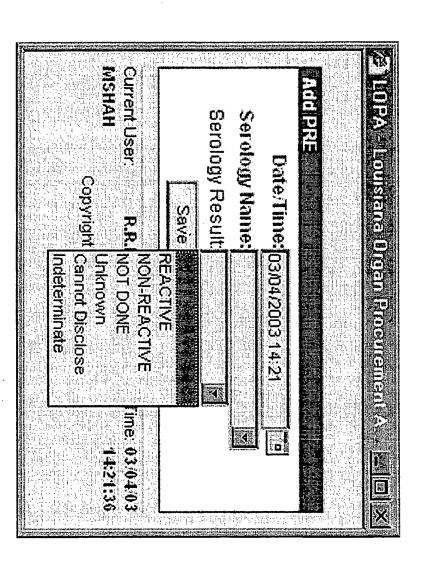


LOPA

### Organ: Serology Results

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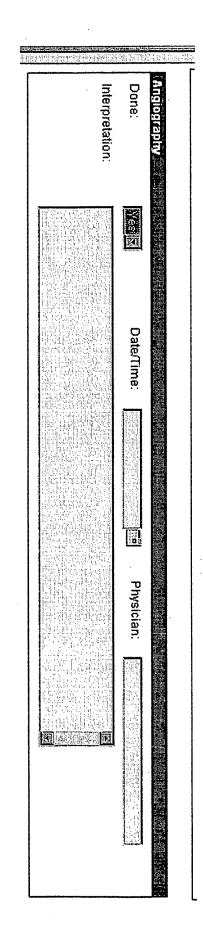
#### Organ: Serology - Adding a serology



### Organ: Cardiac Data

Save Save	Defibrillation/Chest Compressions  Defibrillation Done?	Anglogiaphy (NG) [2]	Cardiac Medications Action  Action  No Cardiac Medications found.  You must saye this page before you can add Cardiac Medications	Echo Readings   EF: BP: Cardiac Rhythm: CO: PAWP: PAWP: FE: BF: BF: BF: BF: BF: BF: BF: BF: BF: BF	Echo: Type: Date/Time: Physi Interpretation:	2 LOPA - Louisiaña Organ Procurement Agency - RRH - Microsoft Internet Explorer
			je     Dosage unit	HR: PA Pressure:	Physician:	

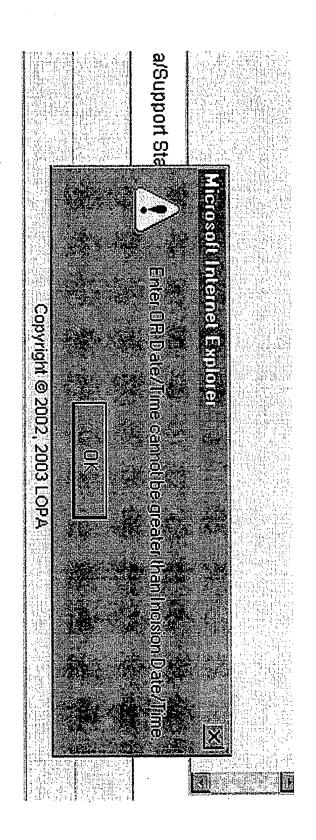
### Organ: Cardiac (dependant fields)



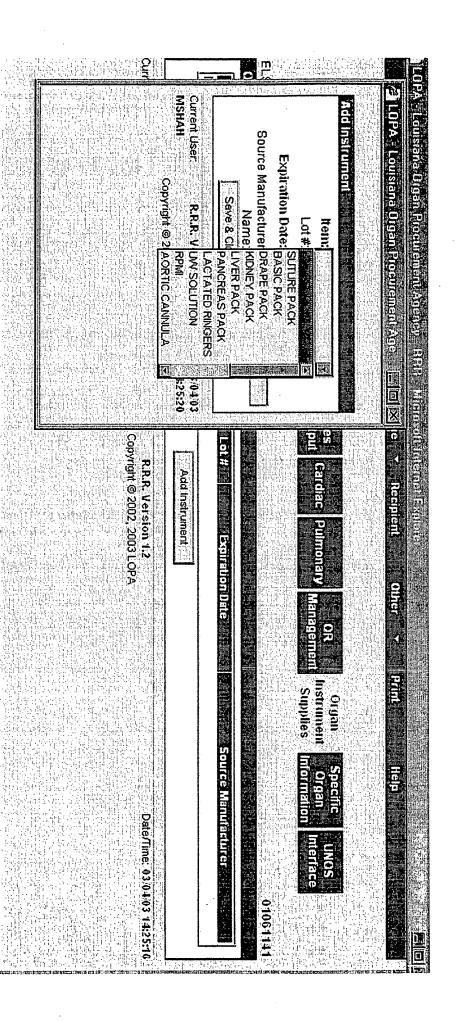
### Organ: OR Management

Save  R.R.R. Version 12  Copyright © 2002, 2003 LOPA	Comments:    Instructions Given to Anesthesia/Support Staff? Oyes @ No	Personnel  Action   Name   Role   Add Hospital Staff   Add Hospital Staff	Other Medications  Action  No Other Medications found.  Add Other Medication	Medications Desage Date/Time  No Medications found.  Add Medication  Add Medication	Crystalloids Type: Crystalloids Volume: Crystalloid	Average Urine Curine Output (cc):  Output (cc):  Blood Products Type 1:  Blood Products Type 2:  Blood Products Type 2:  Blood Products Volume 2:  Blood Products Volume 2:
Date/Time: 03/04/03/1423:54						

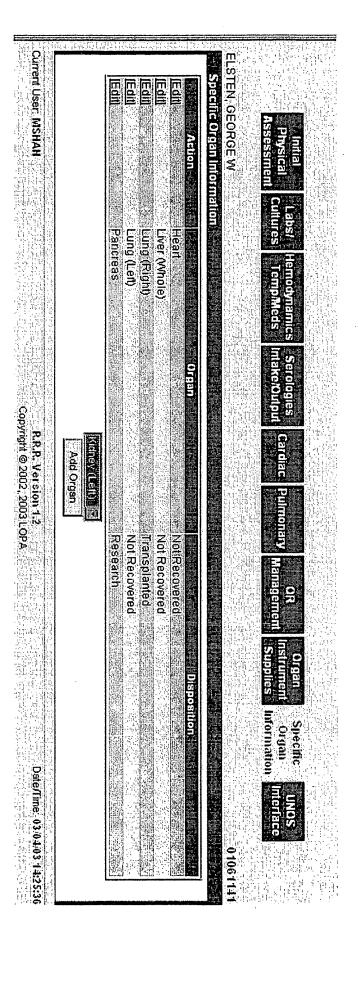
#### Organ: OR Management Example Validation



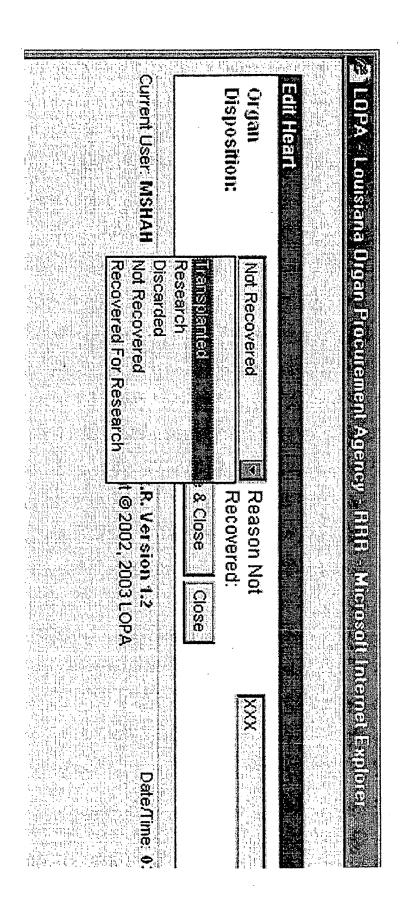
## Organ: Instrument Supplies



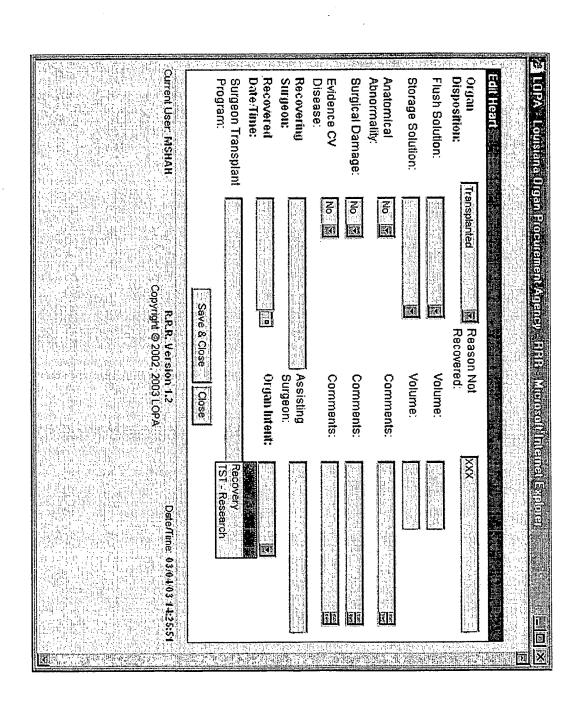
### Organ: Specific Organ Information



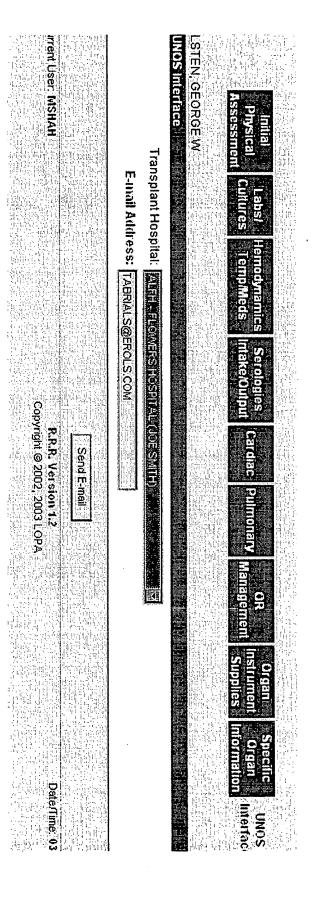
# Organ: Specific Organ- Heart



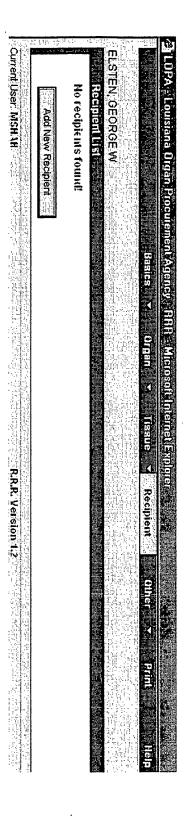
# Organ: Specific Organ - Heart



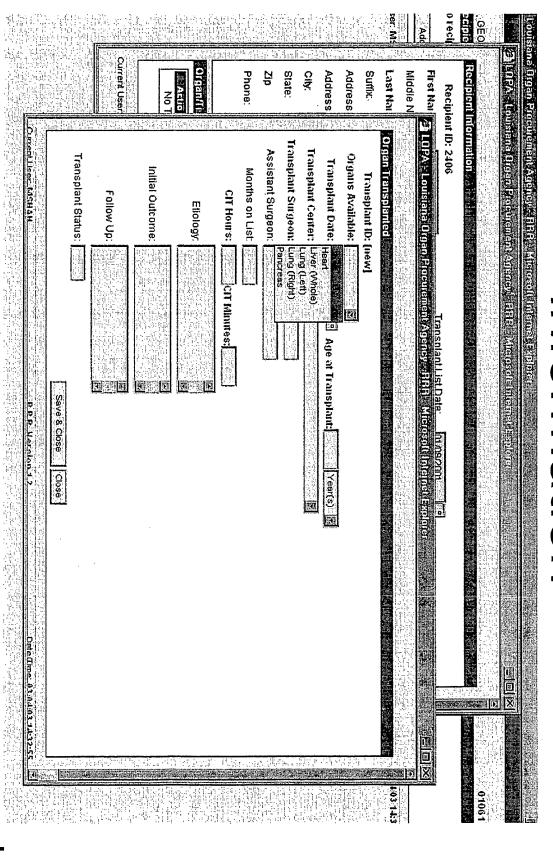
## Organ: Placement



## Recipient Information



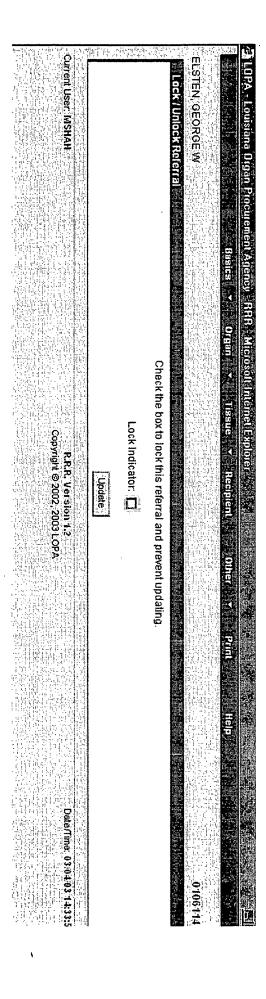
### Recipient: Entering transplant information



### Recipient: Edit Recipient

Ourrent User, MSHAH	No Transplants!	Organ/Lissue Transplanted	Fer. #18.03	Phone:	Zip	State:	City:	Address Line 2:	Address Line 1:	Suffix	ast Name:	Middle Name:	First Name:	Recipient ID: 2406	LOPA - Louisian
	Organ 🥪 📖 Transplant Date 🗽 antsi	ransplarited		(11):111:1111:1111:1111:1111:1111:1111:	11111	American Samoa	NID NID		B	The state of the s		The state of the s	TAMEKA	2406	🤰 LOPA - Louisiana Organ Procurement Agency - RRR - Microsoft
Add Transplant	। । । I ransplant Benter		Save & Close   Close	Blood Group:	Number of Transplants:	Number of Children:	Occupation:	Gender	Birth Date:	SSN:	Race:	Marital Status:	Transplant List Date:		. RAR: Microsoft Internet(Explare
	ा Iransplant Date ा । अधा ransplant Center का । Surgeon v । अधिकारीs on Li			The second secon			STUDENT	O Male O Female	n Age	426-45-2077	African American	Single	01/09/2001		Explorer
Detectine: 03:04:03 74:32:42	กุ!∟ist. ⊴≘  ≧Matches [								Year(s) 🖪						

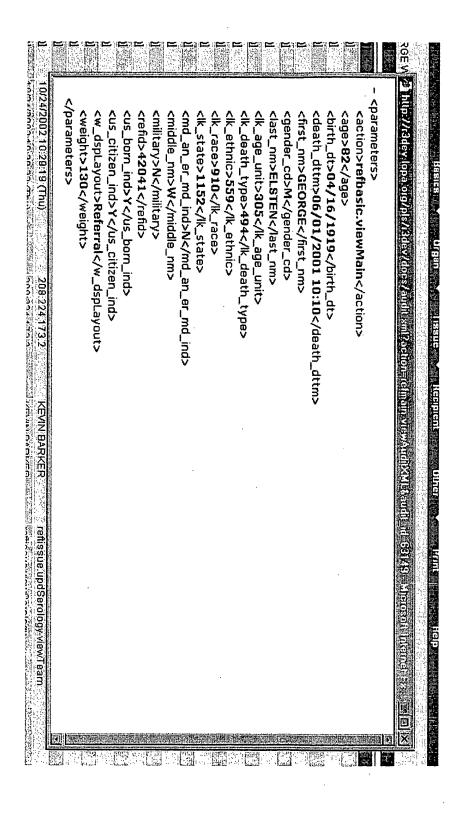
# Quality Assurance: Locking Records



# Quality Assurance: Audit Trai

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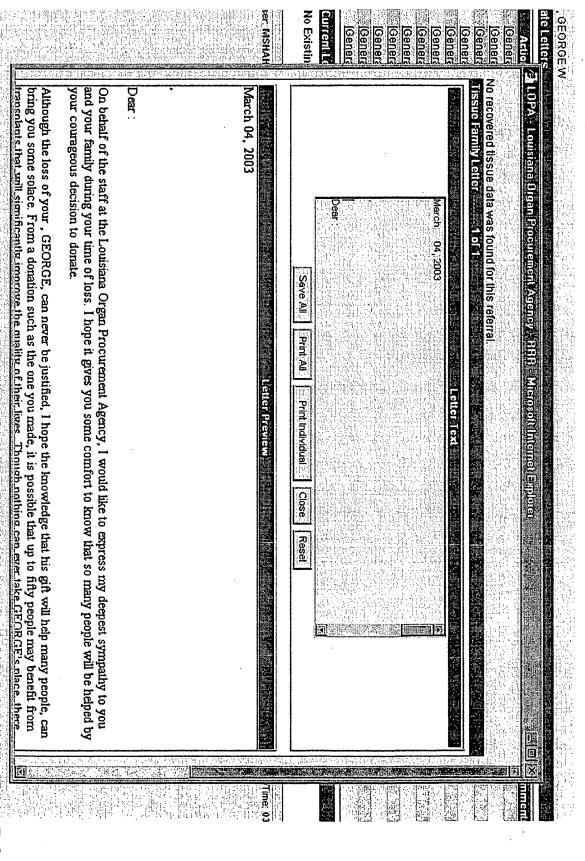
# Quality Assurance: Audit Trai



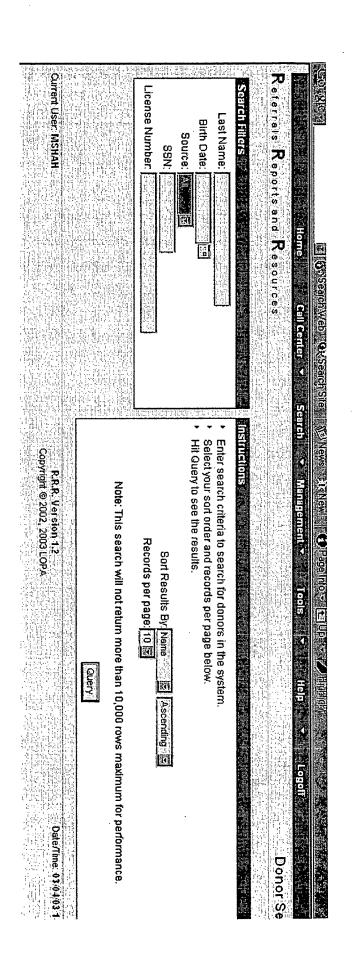
# Referral Tools: Generate Letter

Corrent Use: WSHAH	No Existing Letters!	<u>Generate</u>	<u> Generate </u>	<u>[Generate]</u>	<u>  [Generate]</u>     <u>  [Generate]</u>	<u>[Generate]</u>	[Generate]	<u>Generale</u>	[Generate]	Addition its adverse	Generate Letters	ELSTEN GEORGE W		1 LOPA - Louisiana Organ Proc
		11 Ue 12 De	10 3 M	8	6 Sta	5	100	2 Org	0.00	Letter ID			Basics 🔻 O	Louisiana Organ Procurement Agency - RRH - Microsoft Internet Explorer
, каралия В В		Development Staff Tissue Card	3 Month Organ Followup	Year Organ Followup	Staff Evaluation by Surgeon Recovery MD Letter to Attending MD	lissue CEO Letter	Tissue Staff Letter	Organ Staff Letter	Organ Family Letter				Organ 🔨 Tissue 🐣 Recipient	Microsoft Internet Exploi
R.R.R. Version 1.2 Copyright © 2002; 2003 LOPA		id .			ng MD					Description			Recipient Other	el · · · · · · · · · · · · · · · · · · ·
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	Property of the second												Print Help	

## Other: Generate Letter



## Registry Search



## Add Registry Records

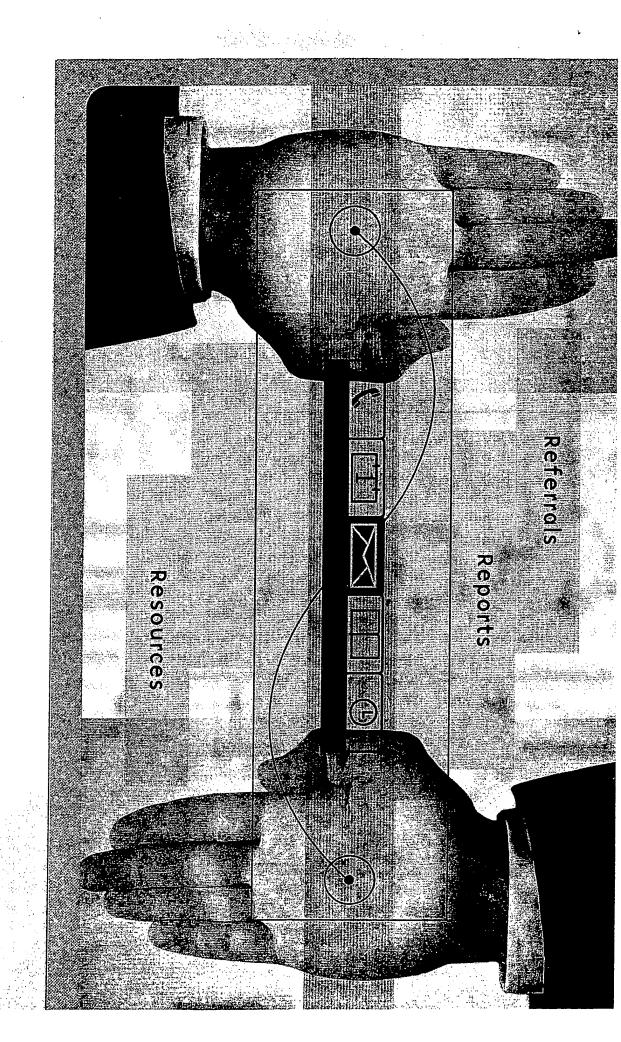
AI Current User, MSHAH	Purpose   Purpos	Organs Marked for Donalion  All Organs Ind  Mindreys Heart  Mindreys Heart  Mindreys Heart  Mindreys Heart	Individual's Name Information  Address Line 1:
Save & Close   Close   Close   Chose   Chose	Regis  Bone Marrow Donor   Blood Bank Donor   Blood Bank Donor	☐ Pancreas ☐ Small Bowels ☐ I	ment Agency   NRR   Microsoft   Internet
	Registry Record Data  Batch Track#  Batchno	Itssues Marked for Donaton	natispline  Middle License SSN Zip
Dede/Time: 03/04/03 14:37:93	Code Recid	☐ Bones Above Walst ☐ Bones Below Waist	

### Questions?



Thank You!





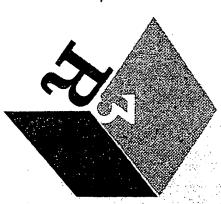
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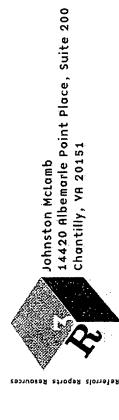
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